UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

FRANCES CLARITY STOKES and THOMAS ALLEN GRAY, Individually and on Behalf of All Others Similarly Situated,

Plaintiffs,

v.

BIOGEN INC., CHRISTOPHER A. VIEHBACHER, MICHEL VOUNATSOS, MICHAEL R. MCDONNELL, and PRIYA SINGHAL,

Defendants.

Civil Action No. 1:24-cv-12691

ORAL ARGUMENT REQUESTED

Leave to file excess pages granted on February 7, 2025 (ECF No. 46)

DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS THE AMENDED COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

Federal Statutes

Defendant Biogen Inc. ("Biogen") and its officers Michel Vounatsos (Biogen's former CEO), Christopher Viehbacher (Biogen's CEO), Michael McDonnell (Biogen's CFO), and Dr. Priya Singhal (Biogen's Executive Vice President and Head of Development) (collectively, the "Individual Defendants," and with Biogen, "Defendants") respectfully submit this memorandum of law in support of their motion to dismiss the First Amended Class Action Complaint (the "Complaint" or "AC"), ECF No. 43.

PRELIMINARY STATEMENT

Biogen is a pioneering biotechnology company that develops and markets highly specialized therapies for some of the most complex diseases in the world. This case focuses on Biogen's FDA-approved, brand-name treatments for multiple sclerosis ("MS") and Alzheimer's disease ("AD"). Plaintiffs claim that nearly fifty statements over a four-year period addressing generic competition for Biogen's MS drugs (Tecfidera and Vumerity), the safety profile for Biogen's AD treatment (Leqembi), and the commercial rollout of Leqembi were false or misleading. In doing so, Plaintiffs try—but fail—to fabricate a claim for securities fraud. The Complaint should be dismissed with prejudice for the following reasons.

First, Plaintiffs do not allege adequately that any of the challenged statements were false or misleading. With respect to statements concerning the performance of Biogen's Tecfidera and Vumerity, including statements that Tecfidera revenue declined after generics entered the market, Plaintiffs do not allege adequately that these statements were false or misleading. Plaintiffs' conclusory assertion that these statements failed to disclose that Biogen had engaged in anticompetitive conduct does nothing to overcome the pleading defects as the Complaint does not adequately allege that Biogen engaged in any such conduct.

Plaintiffs also fail adequately to allege that statements concerning the safety profile of Leqembi were false or misleading. Plaintiffs assert that such statements, several of which merely

relayed information from *the FDA-approved label*, should have included alleged anecdotal and speculative information concerning certain patient deaths. Biogen had no obligation, however, to supplement objective data with the alleged information that Plaintiffs might have found interesting. Moreover, Plaintiffs' failure adequately to allege that statements of scientific opinion about Leqembi were objectively and subjectively false defeats their claims under *Omnicare*.

With respect to statements concerning the commercialization of Leqembi, Plaintiffs challenge statements discussing the progress of the rollout, including references to an aspirational goal to reach 10,000 patients in a particular timeframe. These are either inactionable forward-looking statements protected by the PSLRA safe harbor[1] or statements that are not adequately alleged to be false. That the rollout progressed more slowly than Biogen initially anticipated such that it did not meet the goal does not render the statements false or misleading.

Second, Plaintiffs fail to plead particularized facts showing the required "strong inference" of scienter. The Complaint lacks specific allegations regarding *Defendants'* knowledge of falsity or purported recklessness as to any challenged statements; none of the confidential witnesses describes *any* direct interactions with *any* Individual Defendant during the alleged class period. Plaintiffs also offer no particularized allegations that the alleged information concerning contracts with pharmacy benefit managers, the Leqembi clinical trials, or the Leqembi commercial rollout were conveyed to the Individual Defendants. And Plaintiffs' effort to plead motive by reference to Individual Defendants' stock trading is inadequate to plead scienter, including because the public record shows that the sales alleged either were automatic sales to satisfy tax obligations from the vesting of corporate grants of stock or made pursuant to 10b5-1 plans.

[1] *See* Private Securities Litigation Reform Act, 15 U.S.C. § 78u-4 ("PSLRA").

BACKGROUND[2]

I. Biogen's Multiple Sclerosis Drugs Tecfidera and Vumerity

A. Tecfidera, Vumerity, and Generic Entry

Biogen is a global biotechnology company that discovers and develops groundbreaking treatments for complex diseases including spinal muscular atrophy, MS, and AD. AC ¶ 23. Biogen has been a pioneer in the development of therapies to treat MS. *Id.* ¶ 24. In 2013, the Food and Drug Administration ("FDA") approved a new drug application ("NDA") for Tecfidera. *Id*. ¶¶ 24, 30–32. Available in pill form, Tecfidera answered demand for a treatment more convenient than existing injectable therapies. *Id*. ¶ 24. Tecfidera "soon became the most popular oral medication for the treatment of MS." *Id.* ¶ 25. In 2017, generic manufacturers began challenging Biogen's patents for Tecfidera and filed Abbreviated New Drug Applications ("ANDAs"), which require only that a manufacturer "show that the generic drug is [the] same as the brand name drug in terms of active ingredient, dose, route of administration, and strength" and is "absorbed by the body in the same manner as the brand-name drug[.]" *Id.* ¶¶ 38, 55. On August 17, 2020, the FDA approved the first ANDA for generic Tecfidera. *Id.* ¶ 91. By November 2020, at least eight generic versions of Tecfidera were available, and Biogen's Tecfidera revenue declined. *Id.* ¶¶ 91, 398.

In addition to Tecfidera, Biogen brought to market in 2019 another innovative MS drug known as Vumerity. *Id.* ¶¶ 59, 67. Vumerity is a bioequivalent to Tecfidera, which means that

[2] The background relies on allegations in the Complaint, which are treated as true solely for purposes of this motion to dismiss, "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007); *Lydon v. Loc. 103, Int'l Bhd. of Elec. Workers*, 770 F.3d 48, 53 (1st Cir. 2014). Citations to "Ex." refer to exhibits to the Declaration of Jessica Lewis filed contemporaneously of which Defendants request the Court take judicial notice or which Plaintiffs incorporated by reference into the Complaint.

Vumerity has a different active ingredient than Tecfidera, but "rel[ies] on the same mechanism of action in the human body to produce [its] therapeutic effect." *Id*. Biogen distinguished Vumerity from Tecfidera on the ground that it leads to fewer gastrointestinal problems. *Id.* ¶ 87.

B. Role of Pharmacy Benefit Managers in Tecfidera and Vumerity Sales

Prescription drugs like Tecfidera and Vumerity are sold and paid for in a complex supply chain and payment system that includes manufacturers, distributors, retail pharmacies, and private health plans. *See id.* ¶ 118 (diagram of supply chain). Pharmacy benefit managers ("PBMs") provide services to health plans and "act as middlemen between those payers and the other parties that form part of the prescription drug reimbursement system in the United States." *Id.* ¶ 120. Because of recent corporate consolidation, PBMs have become "powerful intermediaries" in the supply chain. *Id.* ¶¶ 121, 126. PBMs develop drug formularies—lists of prescription drugs that health plans may choose to adopt—which are broken into tiers, with more expensive medications on higher tiers and cheaper medications on lower ones. *Id.* ¶¶ 122–23, 137. PBMs often secure "rebate agreements" with manufacturers, under which manufacturers provide post-sale rebates to the PBM, which the PBM may share with the health plan, in exchange for favorable placement of a manufacturer's drugs on a formulary. *Id.* ¶ 125. As a manufacturer, Biogen entered into rebate agreements with PBMs while selling Tecfidera and Vumerity. *Id.* ¶¶ 146–49.[3]

II. Clinical Trials and Development of Biogen's AD Drug Leqembi

Like MS, AD is a serious but not fully understood neurodegenerative illness. *Id.* ¶¶ 69, 71. One theory is that AD occurs through the buildup of beta-amyloid amino acids ("amyloids") and thus, some scientists believe that medications that target and remove amyloids from the brain can help delay cognitive decline associated with AD. *Id*. ¶¶ 70, 76, 95.

[3] Plaintiffs' allegations about a different AD drug, Aduhelm, are irrelevant to its claims and therefore are not addressed here. *See* AC ¶¶ 78–82, 93–115, 164–82.

In 2014, Biogen entered into a collaboration agreement with Japanese pharmaceutical company Eisai Co., Ltd. ("Eisai") to develop and commercialize treatments for AD, including lecanemab, later known as Leqembi. *Id.* ¶ 77. Eisai led the development of Leqembi and was responsible for "clinical trial management and regulatory filings." *Id.* ¶ 79. Eisai had already conducted a successful Phase 1 trial for lecanemab when it contracted with Biogen, and it initiated a Phase 2 trial of Leqembi around 2014. *Id*. ¶¶ 32, 77 ("Phase 2 Study"). The Phase 2 Study was the first "controlled stud[y] [to] evaluate the effectiveness and side effects" of Leqembi in 856 patients with early AD. *Id.* ¶ 32.[4] On July 24, 2018, Eisai and Biogen released positive topline Phase 2 results, which demonstrated a statistically significant "reduction in amyloid plaques" and "confirmed a dose-dependent slowing in cognitive decline from baseline." July 25, 2018 Eisai and Biogen Phase II Press Release (Ex. 6), Doc. No. 49-6 at 1. Eisai disclosed that the "most common treatment emergent adverse events" were "Amyloid Related Imaging Abnormalities (ARIA)," *id.*, a "serious and sometimes fatal condition seen in AD patients involving transient legions [sic] in the brain that present as 'abnormalities' on MRIs." AC ¶ 109.

In March 2019, Eisai began enrolling patients in the "confirmatory" Clarity Phase 3 Study ("Phase 3 Study"). *Id.* ¶ 165. The Phase 3 Study was a placebo-controlled, double-blind study that "randomized 1,795 people with early [AD] to receive either Leqembi or a placebo" over an 18-month period. *Id*. Participants known to be carriers of ApoE4, a biomarker understood to carry an increased risk of AD, were stratified into a subgroup. *Id.* ¶ 183. Eisai allowed "patients with a broad range of comorbidities/comedications, including hypertension, diabetes, heart disease, obesity, renal disease and anti-coagulants" to participate. Nov. 29, 2022 Eisai and Biogen Phase

[4] *See also* July 25, 2018 Eisai and Biogen Phase II Press Release (Ex. 6), Doc. No. 49-6 at 1. Defendants ask the Court to take judicial notice of this press release because Plaintiffs describe the release of the 2018 Phase 2 Study's topline results, which were announced in this press release. AC ¶ 381; *Pizzuto v. Homology Meds., Inc.*, 2024 WL 1436025, at *1 (D. Mass. Mar. 31, 2024).

3 Press Release (Ex. 8), Doc. No. 49-8 at 1; *see* AC ¶ 283. After the 18-month Phase 3 Study period, participants who previously received the placebo could participate in the "open-label extension," an unblinded extension phase lasting 30 months where Leqembi was made available to all study participants. *Id*. ¶¶ 35, 165. On May 6, 2022, while the Phase 3 Study was ongoing, Eisai requested "accelerated approval" from the FDA for Leqembi based on Phase 2 Study data. *Id.* ¶ 168. The FDA agreed to review the existing Phase 2 data for the purposes of accelerated approval and to later use the Phase 3 study "as the confirmatory study to verify the clinical benefit of lecanemab." May 9, 2022 Eisai and Biogen Press Release (Ex. 7), Doc. No. 49-7 at 1.

By September 27, 2022, the Phase 3 Study was complete; Eisai announced that "lecanemab treatment resulted in highly statistically significant results," and that the study showed a "reduction in amyloid plaque" and met its "primary endpoint by reducing clinical decline on the [relevant cognitive] scale by 27% compared with placebo." AC ¶ 169; Nov. 29, 2022 Eisai and Biogen Phase 3 Press Release (Ex. 8), Doc. No. 49-8 at 1. The study found consistent positive results in the ApoE4 status subgroup. Nov. 29, 2022 Eisai and Biogen Phase 3 Press Release (Ex. 8), Doc. No. 49-8 at 2. "Industry insiders" viewed "the Phase 3 results as a major success." AC ¶ 170.

On November 29, 2022, Eisai presented the full clinical results and its analysis of the Phase 3 data at an industry conference and published "detailed" results in a peer-reviewed journal. *Id.* ¶¶ 169, 174; Nov. 29, 2022 Eisai and Biogen Phase 3 Press Release (Ex. 8), Doc. No. 49-8 at 1. Eisai included data from the open-label extension with a data cutoff of October 22, 2022 in its presentation. AC ¶ 204. Eisai presented on the "Safety Profile of Lecanemab" and disclosed that two deaths had occurred during the open-label extension in which patients displayed "concurrent

macrohemorrhage" at the time of death. *Id.*[5] Eisai also explained that "[r]isk factors" for macrohemorrhage included "ApoE4 genotype" and "anticoagulant medications" (blood thinners). *Id.* In the safety assessment, Eisai noted that patients on blood thinners could continue the open-label extension "with informed consent" on the "increased risk of cerebral hemorrhage with concomitant anticoagulant use." *Id.*

In an accompanying press release, Eisai disclosed that "lecanemab's ARIA incidence profile was within expectations based on the Phase 2 trial results" but that incidents of ARIA occurred more frequently in patients with two ApoE4 alleles. *Id.* ¶ 283. Eisai also disclosed that, although "no deaths were related to lecanemab or occurred with [ARIA]" during the Phase 3 Study, two patients "on lecanemab" died during the open-label extension. *Id.*; Nov. 29, 2022 Eisai and Biogen Phase 3 Press Release (Ex. 8), Doc. No. 49-8 at 1–2. Eisai explained that "[b]oth cases had significant comorbidities and risk factors including anticoagulation contributing to macrohemorrhage or death" and that "[t]herefore, it is Eisai's assessment that the deaths cannot be attributed to lecanemab." AC ¶ 283. A third patient also died in the open-label extension. *Id.* ¶ 192. Each patient death was reported to the FDA. *See id.* ¶¶ 185–86, 191, 193.

On January 6, 2023, based on the Phase 2 data, the FDA granted accelerated approval for Leqembi. *Id.* ¶ 176. Biogen's announcement described the incidence of ARIA in the Phase 2 Study, including that the incidence of symptomatic ARIA was higher in patients with two ApoE4 alleles. Jan. 6, 2023 Biogen Press Release (Ex. 10), Doc. No. 49-10 at 2–4. That same day, Eisai filed for full approval based on the Phase 3 Study data. AC ¶ 176. In later releases, Biogen

[5] The slide contained detailed information about the deaths, including a notation that one of the patients went on and off different blood thinners (apixaban and heparin) and died of cardiopulmonary issues. AC ¶ 204.

summarized Phase 2 and Phase 3 data and gave updates on Leqembi's development.[6] Each press release gave FDA-approved warnings concerning Leqembi, which were consistent with Leqembi's label. *Compare, e.g.*, Jan. 10, 2023 Eisai and Biogen Press Release (Ex. 12), Doc. No. 49-12 at 2–3, *with* Jan. 6, 2023 Leqembi Label (Ex. 22), Doc. No. 49-22 at 2–4.[7] Each recited the clinical data related to the percentage incidence of ARIA; warned: "IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS. LEQEMBI can cause amyloid related imaging abnormalities-edema [ARIA]…"; and disclosed that "[e]vents of intracerebral hemorrhage, including fatal events, in patients taking LEQEMBI have also been reported in other studies."[8]

On July 6, 2023, the FDA granted final approval to Leqembi. AC ¶ 180; *see also* July 6, 2023 FDA Press Release (Ex. 21), Doc. No. 49-21.[9] The FDA called its approval "the first verification that a drug targeting the underlying disease process of [AD] has shown clinical benefit in this devastating disease" and noted that the Phase 3 Study "verified that it is a safe and effective treatment." July 6, 2023 FDA Press Release (Ex. 21), Doc. No. 49-21 at 1.[10] In recognition of the "uncommon but potentially serious side effect" of experiencing ARIA while taking Leqembi, the FDA required a "black box" warning, AC ¶ 180, disclosing that Leqembi could cause ARIA, that "serious and life-threatening events rarely can occur," and that patients with two ApoE4 alleles

[6] *See* AC ¶ 286; Jan. 10, 2023 Eisai and Biogen Press Release (Ex. 12), Doc. No. 49-12; Mar. 5, 2023 Eisai and Biogen Press Release (Ex. 13), Doc. No. 49-13; June 9, 2023 Eisai and Biogen Press Release (Ex. 14), Doc. No. 49-14.

[7] The Court properly can rely on official FDA documents on a motion to dismiss. *See, e.g.*, *Leavitt v. Alnylam Pharms., Inc.*, 525 F. Supp. 3d 259, 266 (D. Mass. 2021).

[8] Jan. 10, 2023 Eisai and Biogen Press Release (Ex. 12), Doc. No. 49-12; Mar. 5, 2023 Eisai and Biogen Press Release (Ex. 13), Doc. No. 49-13; June 9, 2023 Eisai and Biogen Press Release (Ex. 14), Doc. No. 49-14.

[9] The Complaint incorporates this press release by reference. *See* AC ¶ 180 (referring to the FDA's approval); *Leavitt*, 525 F. Supp. 3d at 266.

[10] The FDA noted that "[p]atients treated with Leqembi" who had two ApoE4 alleles "ha[d] a higher incidence of ARIA." July 6, 2023 FDA Press Release (Ex. 21), Doc. No. 49-21 at 2.

who are "treated with this class of medications, including LEQEMBI, have a higher incidence of ARIA[.]" July 6, 2023 Eisai and Biogen Press Release (Ex. 15), Doc. No. 49-15 at 3.

III. Commercial Rollout of Leqembi

Following FDA approval, Eisai and Biogen launched Leqembi. AC ¶¶ 180, 211. On July 25, 2023, Mr. Viehbacher explained that Leqembi was "the very first disease-modifying treatment" to receive "full approval from the FDA and reimbursement" from the Centers for Medicare and Medicaid Services. Biogen 2Q 2023 Earnings Call Tr. (Ex. 17), Doc. No. 49-17 at 1–2; AC ¶ 295. Between July 2023 and February 2024, Biogen gave regular updates and cautioned investors that the rollout was complex and unpredictable. *See, e.g.*, Sept. 11, 2023 Conf. Tr. (Ex. 18), Doc. No. 49-18 at 6; Biogen 3Q 2023 Earnings Call Tr. (Ex. 19), Doc. No. 49-19 at 2–3; Jan. 8, 2024 Conf. Tr. (Ex. 20), Doc. No. 49-20 at 2. Mr. Viehbacher at times referenced a goal of reaching 10,000 patients by March 2024. AC ¶¶ 303–04, 306, 309.

IV. Challenged Statements

Plaintiffs challenge over fifty statements made between September 14, 2020, and November 14, 2024 concerning Biogen's MS and AD treatments, which can be grouped into three categories: (1) statements concerning the commercial impact of generics on Tecfidera and Vumerity, which Plaintiffs allege were somehow misleading because the statements did not disclose that Biogen's rebate contracts with PBMs were supposedly unlawful, AC ¶¶ 225–82; (2) statements concerning Leqembi's safety profile, which were allegedly misleading because the statements did not disclose specific details concerning patient deaths or the potential causes thereof, *id*. ¶¶ 283–99; and (3) statements concerning the commercial rollout of Leqembi, which Plaintiffs allege inaccurately portrayed a goal of treating 10,000 patients by March 2024 as attainable when Biogen allegedly lacked the ability to reach the goal, *id*. ¶¶ 300–16.

LEGAL STANDARD

On a motion to dismiss, the Court must credit well-pleaded facts but need not accept "legal conclusions" or "[t]hreadbare recitals of the elements of a cause of action." *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009). To state a claim under Section 10(b), a plaintiff must adequately plead, among other elements, a material misrepresentation or omission and scienter. *In re Bos. Sci. Corp. Sec. Litig.*, 686 F.3d 21, 27 (1st Cir. 2012). A complaint asserting securities fraud must comply with both the heightened pleading standard of Federal Rule of Civil Procedure 9(b) and the stringent requirements of the PSLRA. *See id.* at 27, 29–30. Under the PSLRA, Plaintiffs must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." *Id.* at 30. Plaintiffs must also allege "with particularity facts giving rise to a 'strong inference' that defendants acted with a conscious intent 'to deceive or defraud investors . . . or 'acted with a high degree of recklessness.'" *Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc.*, 778 F.3d 228, 240 (1st Cir. 2015).

ARGUMENT

I. Plaintiffs Fail to Plead Any Materially False or Misleading Statements[11]

A. Tecfidera and Vumerity Statements Were Not False or Misleading

Plaintiffs allege that Biogen made false or misleading statements because it did not disclose that it was supposedly engaged in anticompetitive conduct. These competition-related statements fall into at least one of three categories: (1) statements describing the performance of Tecfidera and Vumerity, including Tecfidera's decline in revenue due to generic entry; (2) statements describing an "offset" to that revenue decline due to increased Vumerity sales; and (3) statements

[11] Each challenged statement is set forth in the attached Appendix. As explained above, Plaintiffs fail adequately to allege that any statement is false or misleading or was made with scienter.

of corporate optimism regarding the products. Plaintiffs also challenge one statement regarding the function of rebate payments. None of these statements supports a claim.

First, as a matter of law, Plaintiffs do not meet the heightened pleading standards of Rule 9(b) or the PSLRA as to any of the statements. Second, the Complaint fails adequately to allege any underlying "illicit" anticompetitive conduct that could have rendered any challenged statement misleading.

i. *Generic Competition Statements*

Plaintiffs challenge numerous statements describing the negative impact of generic competition on Tecfidera revenue. For example, they challenge a September 2020 statement at an industry conference that "[d]uring the third quarter of 2020, [Biogen] began to experience the impact of multiple Tecfidera generic entrants in the U.S.," AC ¶ 228, and an October 2020 statement in a securities filing that revenues decreases for one drug class "were primarily due to a decrease in Tecfidera demand and pricing as a result of multiple Tecfidera generic entrants entering the U.S. market[.]" AC ¶ 252.[12] Plaintiffs fail to allege that Biogen did *not in fact* experience decreases in revenue from generic competition for Tecfidera. Indeed, the Complaint alleges declines in Biogen's MS product sales, which include Tecfidera, every year since 2018, *id.* ¶ 54, and is replete with allegations showing that generic entry impacted Tecfidera revenues. *See, e.g.*, *id.* ¶¶ 56, 398. Plaintiffs do not plead that the Defendants' statements were false or misleading.

Plaintiffs' baseless theory of "illegality" with respect to Biogen's use of rebates with PBMs does not change the outcome, because the challenged statements on generic competition and Tecfidera and Vumerity performance have no discernable connection to Biogen's use of rebates

[12] These and similar challenged statements were made during industry conferences and several earnings conference calls, and in press releases and quarterly and annual securities filings. *See also* AC ¶¶ 228, 230, 232, 234–35, 237–38, 242, 244, 250–52, 254–56, 258–60, 262–64, 266–68, 270–72, 274, 276, 278, 280–81.

or even its relationships with PBMs. *See, e.g.*, *id.* ¶ 230 (explaining that Biogen "still ha[s] a $6 plus billion business with MS in a highly competitive environment"); *id.* ¶ 234 (describing "first quarter 2021 results" across product lines including MS as "consistent with our expectations . . . despite increased competition"); *id.* ¶¶ 235, 242 (noting that Vumerity's growth "validat[ed] our plan to accelerate the launch" of the drug); *see generally id.* ¶ 250 (describing in securities filing impact of "Tecfidera generic entry" on revenue, without reference to PBMs or rebates).[13] *See, e.g.*, *Backman v. Polaroid Corp.*, 910 F.2d 10, 16 (1st Cir. 1990) (a company must reveal only those facts "that are needed so that what was revealed would not be 'so incomplete as to mislead'").

Plaintiffs also challenge a variety of statements in which Biogen disclosed that a decrease in Tecfidera revenue was "partially offset" by an increase in Vumerity sales. *E.g.*, AC ¶¶ 256, 260, 264, 268, 272, 274, 276, 278, 281. Plaintiffs allege these statements were misleading because Biogen failed to disclose that rebate contracts with PBMs allowed it to stifle generic competition, continue selling Tecfidera at "supracompetitive" prices, and switch patients to Vumerity. *E.g.*, *id.* ¶¶ 227, 247–49; *id.* ¶¶ 253, 257 (statements discussing partial revenue "offsets" due to increased Vumerity sales and "favorable pricing").[14] But Plaintiffs do not plausibly allege that there were *not* increased sales of Vumerity or that those sales did *not* help offset declines in Tecfidera revenue. Moreover, none of the statements implied anything about the role or legality of rebate practices or otherwise gave rise to any obligation for Biogen to accuse itself of anticompetitive conduct. *See Zhou v. Desktop Metal, Inc.*, 120 F. 4th 278, 292–94 (1st Cir. 2024) (statement not misleading for failure to "admit" instance of regulatory non-compliance when challenged statement left "no

[13] *See also* AC ¶¶ 228, 230, 232, 234–35, 237–38, 242, 244, 250–52, 254–56, 258–60, 262–64, 266–68, 270–72, 274, 276, 278, 280–81; *supra* n.12.

[14] *See also* AC ¶¶ 256–57 (alleging statement that decrease in Tecfidera revenue was "partially offset by an increase . . . in Vumerity sales" was false or misleading); *id.* ¶¶ 260–61, 264–65, 268–69, 272–79, 281–82 (similar).

impression about [] regulatory compliance").

Finally, Plaintiffs challenge a handful of statements of "corporate optimism" related to Tecfidera, Vumerity, or the MS product line. For example, Plaintiffs challenge statements such as "[a]s long as we can innovate, we continue to do well" and statements touting "Vumerity's strong product profile." *See* AC ¶¶ 225–26; ¶ 237.[15] The First Circuit has routinely held that this kind of statement and the similar statements catalogued in footnote 15 cannot support a claim for securities fraud. *Thant v. Karyopharm Therapeutics, Inc.*, 43 F. 4th 214, 223 (1st Cir. 2022) ("important milestone" and "significant step in establishing the efficacy and safety [of drug]" inactionable); *State Tchrs. Ret. Sys. of Ohio v. Charles River Labs. Int'l, Inc.*, 2024 WL 3258293, at *11 (D. Mass. July 1, 2024) (same as to statements that company was "doing very well resourcing [subjects]" for safety assessment studies).

ii. *Plaintiffs Fail to Allege That Biogen's Use of Rebates Was Unlawful*

Plaintiffs fail to establish the underlying premise for their assertion that Biogen's failure to disclose its alleged "illicit" use of rebates rendered the above statements false or misleading. As an initial matter, Plaintiffs do not allege that it is illegal for manufacturers to pay rebates to PBMs. Nor do they point to any adjudication or legal authority establishing that Biogen's (or any other manufacturer's for that matter) use of rebates was illegal. For example, although the Complaint references a pending 2024 FTC administrative action against *PBMs* (which has not yet been adjudicated), *see* AC ¶ 334, it does not suggest that any such action has been brought against

[15] *See also* AC ¶ 230 (describing MS business as "highly competitive environment" and Vumerity product "demonstrating some good signs"); *id.* ¶232 (explaining belief that "these results demonstrate our ability to maintain leadership and execute well despite increased competition [and] the erosion of Tecfidera revenue in the U.S."); *id.* ¶ 235 (noting that Vumerity's growth "is a testament to a strong product profile and our team's ability to execute well . . ."); *id.* ¶¶ 242, 244 (similar); *id.* ¶ 239 (explaining that Biogen "welcome[s] new players," and "some of them being competition"); *id.* ¶ 241 (similar).

Biogen or any other drug manufacturer, let alone that any proceeding has resulted in a determination that any of Biogen's conduct was anticompetitive. Moreover, the Complaint makes no effort to plead the basic components of an antitrust claim, including "proof that the defendant exercises or could exercise a threshold degree of market power, which is the defendant's power to lessen or eliminate competition in the relevant market." *See, e.g.*, *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *4 (D. Mass. Jan. 25, 2018) (citing 15 U.S.C. § 1). Similarly, despite referring to rebates as "kickbacks," the Complaint does not explain how the rebates allegedly violate any anti-kickback or other law. AC ¶¶ 135, 138, 144, 150–52, 155.[16]

None of Plaintiffs' other allegations supports an inference of unlawful conduct. The confidential witnesses ("CWs") merely provide general allegations about how Biogen operates, the timing of its rebate contracts, and its strategy to switch patients to Vumerity. *See id.* ¶¶ 146–47 (CW5 explaining that Biogen, "like any major pharmaceutical company, had a [p]ricing [c]ommittee"; CW1 and CW2 explaining that rebate contracts required executive approval); *id.* ¶ 146 (CW2 alleging that, following the Tecfidera patent invalidation, Biogen implemented rebate contracts); *id.* ¶ 67 (CW3 alleging corporate level strategy to "try to transfer as many patients as possible from Tecfidera to Vumerity"). CW4 vaguely described a need to increase prices because of "fees" paid to PBMs, *id.* ¶ 145, but did not claim anyone at Biogen believed this was unlawful; in any event, CW4 did not even work at Biogen during the alleged class period, *id.* ¶ 15.

Rather than allege facts supporting their claim, Plaintiffs merely conclude that "Biogen's

[16] Plaintiffs' allegations that, Humana Inc. (which Plaintiffs allege operates a PBM) filed a lawsuit against "Biogen for causing it to reimburse prescriptions for Biogen's MS drugs that were the result of an illegal kickback scheme" change nothing as those allegations pertains only to conduct from 2014-2017, which significantly predates the alleged class period. *See, e.g.*, AC ¶¶ 144, 150–52. Plaintiffs do not allege any connection between those dated accusations and the relevant period in this litigation.

entry into illicit rebate contracts" with PBMs "suppressed" competition. *Id.* ¶ 253.[17] But Biogen had no obligation to adopt and disclose Plaintiffs' baseless characterization of its use of rebates. *See Hill v. Gozani*, 638 F.3d 40, 59 (1st Cir. 2011) (company "had no obligation to make…public" expert opinion that its billing practices were unlawful). Where courts have found statements misleading for failure to disclose unlawful conduct, that conduct has been adjudicated to be illegal or the law was clear, and the complaint "specif[ied] what law or standard the defendant violated and how the alleged violation occurred." *See, e.g.*, *Mart v. Tactile Sys. Tech., Inc.*, 595 F. Supp. 3d 788, 808 (D. Minn. 2022). Plaintiffs show neither. Accordingly, Biogen's failure to disclose "illicit" conduct cannot render statements false or misleading by omission or otherwise.

B. Leqembi Statements Were Not False or Misleading

Plaintiffs challenge statements concerning the safety profile of Leqembi and its commercial rollout, but do not allege adequately that any statement in either category was misleading.

i. *Leqembi Safety Profile Statements*

Plaintiffs challenge a series of statements concerning different phases of the Leqembi clinical trials and interpretations of the resulting data. *See* AC ¶¶ 283, 285–86, 288, 290, 292–93, 296. Plaintiffs' principal contention is that these statements misled investors as to Leqembi's "safety profile" because the statements did not reference one specific patient death and did not contain certain alleged anecdotal information or individual opinions that allegedly would have supported *Plaintiffs'* views that Leqembi had caused certain patient deaths. *Id.* ¶¶ 284, 287, 289, 291, 294, 297, 299. These contentions do not satisfy Plaintiffs' heightened pleading obligations.

1. Phase 3 Study Data Presentation and Subsequent Analyses

First, Plaintiffs challenge the November 2022 press release announcing the Phase 3 Study

[17] *See also* ¶¶ 257 (describing "illicit rebate contracts . . . that suppressed sales from generic versions of Tecfidera"); *id.* ¶¶ 261, 265, 269, 273, 277, 279, 282 (similar).

data, though they do not deny the Study showed both a reduction in amyloid plaques and an improvement on the relevant cognitive decline metric. *See id.* ¶¶ 169, 283. Rather, Plaintiffs assert that the representation that there had been "two cases" of deaths with "concurrent cerebral macrohemorrhage" and Eisai's "assessment that the deaths cannot be attributed to lecanemab" misled investors about Leqembi's safety profile. *Id.* ¶¶ 283–84. Not so.

As an initial matter, the Complaint undermines Plaintiffs' claim that the November 2022 press release should have disclosed that "three patients"—instead of two—died in the open-label extension phase after taking Leqembi. Full information about Patient 3's death, including autopsy information, was not yet available in November 2022. *Id.* ¶¶ 196–97 (alleging Patient 3's autopsy not performed until March 2023 and results not provided to "relevant parties" until late March/early April 2023); *id.* ¶ 193 (following Patient 3's death, "new information" continued to "[come] in" related to her death, including "hospital records[] and MRIs").[18] Similarly, any contemporaneous "conclusions" that other medical professionals drew as to the cause of death were reached before all relevant information was available. *See, e.g.*, *id.* ¶ 207 (article describing December 2022 opinions of neurologists and recognizing autopsy not yet performed). Indeed, the trial investigator responsible for Patient 3 only "preliminarily" classified the death as "related" to Leqembi "*pending receipt of MRI scans and the autopsy report*." *Id.* ¶ 193 (emphasis added).

To the extent Plaintiffs disagree with Eisai's "assessment" that the patient deaths "[could not] be attributed to lecanemab," that difference of scientific opinion does not give rise to a securities fraud claim unless the opinion was objectively and subjectively false. *Pizzuto*, 2024 WL 1436025, at *9 (no falsity alleged where plaintiffs did not allege that discussions about clinical

[18] Further, the November 2022 release of the Phase 3 Study results had a data cutoff date of October 22, 2022, which further pre-dated Patient 3's death. AC ¶ 204; *Pizzuto*, 2024 WL 1436025, at *8 ("[W]here statements are limited to data before a specified cutoff date, they cannot be considered misleading by 'clinical data that occurred after that cut-off date.'").

trial data "directly contradicted the undisclosed information"); *In re Karyopharm Therapeutics Inc., Sec. Litig.*, 552 F. Supp. 3d 77, 90 (D. Mass. 2021) (discrepancy with FDA's calculation of data was "non-actionable scientific disagreement"); *Corban v. Sarepta Therapeutics, Inc.*, 2015 WL 1505693, at *6 (D. Mass. Mar. 31, 2015) (no falsity alleged where plaintiffs failed to allege that defendants "did not subjectively believe" interpretations of clinical trial data); *Leung v. Bluebird Bio, Inc.*, 599 F. Supp. 3d 49, 63 (D. Mass. 2022) (collecting cases). The Complaint does not plausibly allege that information Defendants allegedly relied on was anything other than what Eisai reported or that any undisclosed information directly contradicted Eisai's public assessment. Nor does the Complaint allege that Eisai, Biogen, or *any* of the Individual Defendants did not genuinely believe Eisai's opinion.

Further, to plead falsity, Plaintiffs must show that the omitted information—namely, the third patient death from the open-label extension and anecdotal opinions about the cause of death—rendered the November 2022 press release "so incomplete as to mislead." *Karyopharm*, 552 F. Supp. 3d at 86. That press release disclosed the deaths of two patients with "concurrent cerebral macrohemorrhage" from the open-label extension. AC ¶ 283. The additional information might have been interesting to investors, but its omission did not mislead them. *See Thant*, 43 F.4th at 226 (no liability where company did not "include data on…prevalence of serious [adverse events]" in clinical data reporting even though plaintiff "may have wished to know more" about adverse events); *Pizzuto,* 2024 WL 1436025, at *8; *Leung*, 599 F. Supp. 3d at 69.

Second, Plaintiffs challenge statements from March and April 2023 regarding an additional analysis Eisai conducted on the Phase 3 study dataset. AC ¶¶ 290, 292. Eisai used the Phase 3 study dataset to compare rates of ARIA in Phase 3 Study participants on blood thinners to those not on blood thinners. *Id.* On March 30, 2023, Biogen announced that, based on this analysis,

"ARIA did not occur more frequently in [Leqembi]-treated participants" on blood thinners. *Id.* ¶ 290. During an April 25, 2023 earnings call, Dr. Singhal shared highlights from this analysis and paraphrased the same conclusion. *Id.* ¶ 292. Plaintiffs assert that these statements misled the public about the safety risk of ARIA in Leqembi patients because Biogen did not discuss the three patients who died during the Phase 3 open-label extension study (including that they were on blood thinners and who also had two ApoE4 alleles). *Id.* ¶¶ 291, 294. But again, Plaintiffs do not allege the statements were not accurate and, as explained above, Biogen had no obligation to supplement objective statistical findings with other anecdotal information or opinions. *See Thant*, 43 F.4th at 226. As such, these statements fail to support a claim.

2. January 6, 2023 Accelerated Approval Announcement and Subsequent Statements

Plaintiffs also challenge a January 6, 2023 press release that announced the FDA's accelerated approval of Leqembi, described the Phase 2 results, restated certain risk-related sections of Leqembi's label, and explained that Eisai would seek traditional FDA approval based on the "recently published data from the large global confirmatory Phase 3 [Study]." Jan. 6, 2023 Biogen Press Release (Ex. 10), Doc. No. 49-10 at 1; *see* AC ¶ 285. Plaintiffs challenge similar disclosures in press releases on January 10, 2023, March 5, 2023, and June 9, 2023. AC ¶ 286.

Plaintiffs take issue with statements in press releases that "[e]vents of intracerebral hemorrhage, including fatal events" and "incidence of symptomatic and overall ARIA" in patients with two ApoE4 alleles have "been reported in *other studies.*" *Id.* ¶¶ 285–86 (emphasis added). This language mirrored the FDA-approved label for Leqembi and clearly reprinted "IMPORTANT SAFETY INFORMATION" and "WARNINGS AND PRECAUTIONS" from the label.[19] Jan. 6,

[19] *Compare* AC ¶ 285, *with* Jan. 6, 2023 Leqembi Label (Ex. 22), Doc. No. 49-22 at 4–7 (listing "WARNINGS AND PRECAUTIONS" using identical or near-identical language to press release).

2023 Biogen Press Release (Ex. 10), Doc. No. 49-10 at 2. In addition, each press release included the FDA-approved warning ("LEQEMBI can cause amyloid related imaging abnormalities-edema [ARIA]…") and described the incidence of ARIA in study participants, including the number of ApoE4 carriers relative to the incidence of ARIA. *Id.* at 2–3. Plaintiffs completely ignore this disclosure and the use of language from the FDA-approved label. *See Pizzuto*, 2024 WL 1436025, at *12 (no falsity where "total mix of information" included "[company]'s disclosure of the risks at issue," which "sufficiently disclosed the overall risk"); *Karyopharm*, 552 F. Supp. 3d at 88.

Instead, Plaintiffs complain that the reference to "other studies" did not explicitly identify the Phase 3 Study open-label extension, which, they say, "gave the false impression" that there "were no such events in the recently completed Phase 3 study." *Id.* ¶ 287. This argument strains credulity. These press releases were published *after* Eisai released the Phase 3 Study results in November 2022. The November 2022 announcement contained information about the "fatal events" at issue and the incidence of ARIA in patients with two ApoE4 alleles that occurred in the open-label extension study, which is a separate study from the placebo-controlled, 18-month Phase 3 Study. *See, e.g.*, *id.* ¶¶ 165, 283. Accordingly, Biogen had disclosed fatalities in the Phase 3 open-label extension study and therefore did not conceal anything.[20] *See In re The First Marblehead Corp. Sec. Litig.*, 639 F. Supp. 2d 145, 155 (D. Mass. 2009) (no falsity based on theory of concealed information "if that information was, in fact, disclosed"); *see also Ponsa-Rabell v. Santander Secs.*, 35 F.4th 26, 35 (1st Cir. 2022) (similar).

[20] Plaintiffs challenge a similar statement from a January 6, 2023 Eisai press release (to which Biogen included a hyperlink on its website), also derived from the Leqembi label: "[e]vents of intracerebral hemorrhage, including fatal events, in patients taking Leqembi have also been reported." AC ¶ 288. Even if Biogen could somehow be held responsible for Eisai's press release, which it cannot, *cf. Janus Cap. Grp., Inc. v. First Deriv. Traders*, 564 U.S. 135, 146–48 (2011) (subsidiary acting as advisor to parent company not liable for misstatements made by parent), Plaintiffs do not explain why this statement was false or misleading. AC ¶ 288.

3. Statements Following FDA Approval

Plaintiffs also challenge statements after the FDA's final approval in which Individual Defendants expressed their opinions that the benefits of Leqembi outweighed the risks. AC ¶¶ 295–96, 298. For example, Plaintiffs challenge Mr. Viehbacher's July 25, 2023 statement that he "[thought] the safety benefit of lecanemab w[ould] be quite important to physicians as we go forward" and statements by Dr. Singhal about Leqembi's benefit-risk profile. *Id*.

At the time of these statements, the FDA already had weighed the benefits and risks of Leqembi and determined that it "is a safe and effective treatment for patients with [AD]." July 6, 2023 FDA Press Release (Ex. 21), Doc. No. 49-21 at 1. The challenged statements echoed these findings and opined that physicians would and should make similar assessments. These are classic nonactionable opinions that are not alleged to be objectively or subjectively false when made. *Harrington v. Tetraphase Pharms. Inc.*, 2017 WL 1946305, at *5 (D. Mass. May 9, 2017) ("[C]ourts have been clear that scientific opinions are just that: opinions."); *see supra* 16–17.[21]

ii. *Leqembi Commercial Rollout Statements*

Plaintiffs also challenge a series of statements made during the first eight months after traditional FDA approval in which Biogen described the status of its commercialization efforts. AC ¶¶ 300–02 (July 25, 2023 earnings call); ¶¶ 303–05 (September 11, 2023 healthcare conference); ¶¶ 306–07 (November 8, 2023 earnings call); ¶¶ 308–10 (January 8, 2024 healthcare conference); ¶¶ 311–12 (January 31, 2024 press release); ¶¶ 313–16 (February 13, 2024 earnings call). Plaintiffs allege that these statements—which include statements describing a goal of

[21] Similarly, Individual Defendants made statements relaying their understanding of clinical trial data, which are statements of opinion not adequately alleged to be false or misleading or not believed by the Individual Defendants. *See* AC ¶ 292 ("[t]he results" of Phase 3 Study "were encouraging" based on data "Eisai recently presented"); *id.* ¶ 293 (Eisai "presented some of these data" related to double ApoE4 carriers and "believe[s] . . . the data set was rather small" and "don't believe that the overall conclusions are different").

reaching 10,000 patients by the end of March 2024—were false or misleading because Biogen did not disclose that it had "no infrastructure" to sell Leqembi, "no visibility" into progress made toward the goal, "no basis" for the goal, and "no realistic ability" to meet it. *E.g.*, *id.* ¶¶ 302, 307, 312, 316. But the majority of the statements are either forward-looking statements protected under the PSLRA safe harbor or are descriptions of the status of the commercial rollout that are not adequately alleged to be false. The remainder are statements of inactionable corporate optimism.

1. 10,000 Patient Goal Statements

Plaintiffs challenge statements describing Eisai's goal of reaching 10,000 patients by the end of March 2024, to which Biogen aspired. Three communications—made on September 11, 2023, November 8, 2023, and January 8, 2024—refer to the 10,000-patient goal. *E.g.*, *id.* ¶¶ 303–04 (referencing "target of 10,000" and stating "nothing that we're seeing says that the Eisai guidance can't be met, which is 10,000 patients by … the end of March"); *id.* ¶ 306 (stating that "we have an aim of getting to 10,000 patients by the end of March"); *id.* ¶ 309 (referencing "target of 10,000"). These statements are inactionable under the PSLRA safe harbor because they are forward-looking and either (1) were both identified as forward-looking and accompanied by meaningful cautionary language or (2) not alleged to have been made with actual knowledge of falsity. *See* 15 U.S.C. §§ 78u–5(c)(1).

As an initial matter, each of the statements referred to is a forward-looking statement. For example, on September 11, 2023, Mr. Viehbacher spoke about the launch of Leqembi at a conference and noted that "nothing that we're seeing says that the Eisai guidance can't be met, which is 10,000 patients *by … the end of March*." AC ¶ 303; Sept. 11, 2023 Conf. Tr. (Ex. 18), Doc. No. 49-18 at 6. He also described developments with a patient registry and expectations that the registry would not limit patient uptake. AC ¶ 303 ("now we can go. There's no limitation … the registry seems to be pretty easy to operate"). On November 8, 2023, Mr. Viehbacher

referenced "an aim of getting to 10,000 patients *by the end of March*" during a quarterly earnings call with analysts. AC ¶ 306 (emphasis added). Finally, on January 8, 2024, Mr. Viehbacher addressed the status of the launch at a conference and referenced the future "target of 10,000." AC ¶ 309; Jan. 8, 2024 Conf. Tr. (Ex. 20), Doc. No. 49-20 at 2. These statements are not adequately alleged to have been false or misleading when made and, in any event, are inherently forward-looking statements describing a future goal. *See In re Analogic Corp. S'holder Litig.,* 2019 WL 4804800, at *8–9 (D. Mass. Sept. 30, 2019) ("plans and objectives of management for future operations" are forward-looking); 15 U.S.C. § 78u–5(i)(1) (defining "forward-looking statement" to include plans for future operations).

First, the statements during the November 8, 2023 quarterly earnings call fall under the safe harbor because they were explicitly identified as forward-looking and accompanied by meaningful cautionary language, including referring to risk factors in SEC filings and outlining other risks. *See* 15 U.S.C. §§ 78u–5(c)(1)(A)(i); Biogen 3Q 2023 Earnings Call Tr. (Ex. 19), Doc. No. 49-19 at 2–3 (noting "complexity" and that industry changes to facilitate launch "take[] time"); Biogen 2Q 2023 Form 10-Q (Ex. 3), Doc. No. 49-3 at 3; Biogen 3Q 2023 Form 10-Q (Ex. 4), Doc. No. 49-4 at 3. These cautions were sufficient to invoke the safe harbor's protection. *See Hackel v. AVEO Pharms., Inc.*, 474 F. Supp. 3d 468, 480, 483 (D. Mass. 2020) (safe harbor applied where speaker referred back to risks in SEC filing); *Tetraphase*, 2017 WL 1946305, at *9 (short cautionary statement of risks sufficient to trigger PSLRA safe harbor).

Moreover, Mr. Viehbacher repeatedly framed the 10,000 figure as a goal, not a guarantee, and cautioned investors about challenges with the rollout. AC ¶ 306 ("aim of getting to 10,000 patients"); *id.* ¶¶ 304, 309 ("target of 10,000"); *see, e.g.*, Sept. 11, 2023 Conf. Tr. (Ex. 18), Doc. No. 49-18 at 6 (describing launch as "logistically a major exercise" and "a heavy-lift"); Biogen

3Q 2023 Earnings Call Tr. (Ex. 19), Doc. No. 49-19 at 3 (noting "complexity" and that industry changes to facilitate launch "take[] time"); Jan. 8, 2024 Conf. Tr. (Ex. 20), Doc. No. 49-20 at 3, 7 (explaining that "there are no real analogues for" a "pioneering" launch). That Biogen and Eisai did not reach the 10,000-patient goal because of challenges Mr. Viehbacher previewed does not render earlier statements false. *See Ganem v. InVivo Therapeutics Holdings Corp.*, 845 F.3d 447, 456–57 (1st Cir. 2017) ("fraud by hindsight" does not state securities fraud claim).[22]

Second, the statements about the 10,000-patient goal also are protected under the safe harbor because Plaintiffs fail to plead Defendants' "actual knowledge" of falsity. 15 U.S.C. § 78u–5(c)(1)(B). The safe harbor "ratchets the [pleading standard] bar even higher" than Rule 9(b)'s particularity requirement and requires Plaintiffs to allege actual knowledge of falsity when challenging forward-looking statements like goals or predictions. *See In re Praecis Pharms., Inc. Sec. Litig.*, 2007 WL 951695, at *9 (D. Mass. Mar. 28, 2007). Here, Plaintiffs come nowhere close to meeting this demanding standard. The Complaint does not adequately allege that any of the Individual Defendants had actual knowledge of the allegations on which the Plaintiffs base their inadequately pled claims of falsity (*e.g.*, that Biogen "had no infrastructure in place to effectively sell Leqembi," or "had no visibility" into progress being made toward the goal," AC ¶ 302, and the other such allegations which Plaintiffs make in AC ¶¶ 300–16). See *Coyne v. Metabolix, Inc.*, 943 F. Supp. 2d 259, 268 (D. Mass. 2013) ("conclusory and vague" allegations that defendants lacked "rational basis" for misrepresentations were insufficient to remove safe harbor protection).

[22] Moreover, in addition to being protected under the safe harbor, some portions of these challenged statements are additionally inactionable as accurate statements of historical fact that are not adequately alleged to be false or misleading. *See, e.g.*, AC ¶¶ 304 (discussing "key metric" and how field force is "busy on all of the logistics"); *id.* ¶ 306 (discussing "signs of progress" and "internal metrics"); *id.* ¶ 308 (explaining "rush" and need to "look upstream" for indicators of progress); *id.* ¶ 309 (discussing lack of capacity constraints); *see Tharp*, 321 F. Supp. 3d at 227, 230 (dismissing complaint and finding "accurate reports of past successes" inactionable).

2. Statements About Status of Leqembi Commercial Launch

Plaintiffs also challenge statements made on three specific dates—July 25, 2023, January 31, 2024, and February 13, 2024—that describe the status of Biogen's commercialization of Leqembi. AC ¶¶ 300–01, 311, 314–15. Confusingly, Plaintiffs maintain that these statements—none of which reference the 10,000-patient goal—were false or misleading because they discuss "Biogen's preparedness" to meet the 10,000-patient goal without disclosing that Biogen allegedly "had no realistic ability" to meet the goal. *Id.* ¶¶ 302, 312, 316. This argument fails.

First, Plaintiffs challenge statements by Mr. Viehbacher during a July 25, 2023 earnings call, just weeks after Leqembi received traditional approval, that "the launch is going to plan," that Biogen had "deploy[ed] [its] resources," and that the field organization, comprise of "a lot of people," was "geared up" for launch. *Id.* ¶¶ 300–01. Plaintiffs allege that these statements were misleading because Biogen lacked sales infrastructure and visibility into progress towards the goal. *Id.* ¶ 302. The statements merely convey that Biogen's sales organization was preparing for the launch and that Biogen was deploying its resources to support it. *See Backman*, 910 F.2d at 16 (a company must reveal only those facts "that are needed so that *what was revealed* would not be 'so incomplete as to mislead'" (emphasis added)). Moreover, the Complaint does not allege that these efforts were not, in fact, "going to plan" at the time the statements were made just weeks after FDA traditional approval. *See* AC ¶ 301; *Premca Extra Income Fund LP v. iRobot Corp.,* 2025 WL 307247, at *22 (D. Mass. Jan. 27, 2025) (dismissing claims because allegations were "insufficient to plead that any of the updates and regulatory statements were false when made").

Next, Plaintiffs challenge the statement from January 31, 2024 that, because Biogen had discontinued another AD drug, it would redeploy "resources" from that program to "Biogen's AD franchise." *Id.* ¶ 311; Jan. 31,2024 Biogen Press Release (Ex. 16), Doc. No. 49-16 at 2. This statement cannot have misled the public about Biogen's "ability to meet the 10,000 Patient Goal"

because it nowhere discusses the goal. *See Backman*, 910 F.2d at 16. But even if it did, the Complaint does not allege that Biogen was *not* redeploying resources to the Leqembi rollout such that it would render the statement false or misleading. *See id.*

Finally, Plaintiffs challenge statements by Mr. Viehbacher from the February 13, 2024 quarterly earnings call that commented on Biogen's "very solid progress" in "validat[ing] the go-to-market model" and "driv[ing] growth" for Leqembi. AC ¶¶ 314–15. The statements also estimated that there were "approximately 2,000 patients on [Leqembi] therapy at the moment" and stated that "we have an indication that there are about 3,800 patients as of last week on the registry" for Leqembi enrollment. *Id.* ¶ 315. Plaintiffs do not allege that Biogen had *not* made such progress or that there were *not* approximately 2,000 patients on Leqembi and 3,800 patients on the registry. Indeed, the Complaint includes allegations *consistent* with such estimates. *See id.* ¶¶ 306, 315 (alleging that Biogen expanded Leqembi access from 800 patients in November 2023 to 2,000 in February); *id.* ¶ 308 (describing increased numbers of patients on registries and increased activity for certain scans and diagnostics that are pre-cursers to Leqembi treatment). Here, "plaintiffs undermine their own assertion" of false or misleading disclosures "[w]ith conflicting allegations." *In re Stone & Webster, Inc. Sec. Litig.*, 253 F. Supp. 2d 102, 121 (D. Mass. 2003).[23]

3. Statement of Corporate Optimism About Leqembi Commercialization

The remaining statements concerning the Leqembi rollout are inactionable statements of corporate optimism that expressed general positive views of Biogen's efforts. *See* AC ¶¶ 306

[23] To the extent that Plaintiffs allege that Mr. Viehbacher, Mr. McDonnell, or Dr. Singhal "failed to correct" certain of the challenged statements, *see* AC ¶¶ 302, 307, 310, 316, these allegations also fail to state a claim because Plaintiffs do not plead that any speaker learned that a prior statement was misleading when made because of specific, later-discovered errors. *See Backman*, 910 F.2d at 16–17; *In re Burlington Coat Factory Sec. Litig*, 114 F.3d 1420, 1432–33 (3d Cir. 1997) (requiring allegations as to what specific errors made forecast misleading).

("we're pioneering this commercial approach"); *id.* ¶ 308 (describing "positive data" and "an awful [lot] of tremendous progress on LEQEMBI"); *id.* ¶ 314 ("we are not just pioneering in science but pioneering in commercial"). Such statements do not support a claim for securities fraud. *E.g.*, *Thant*, 43 F. 4th at 223 (statements like "important milestone" and "significant step in establishing [] efficacy and safety" are corporate optimism).

II. Plaintiffs Fail to Plead Allegations Supporting a Strong Inference of Scienter

A. No Scienter as to Tecfidera and Vumerity Statements

Plaintiffs' failure to allege that Biogen engaged in any illicit anticompetitive activity necessarily means that they have not pled scienter for statements that allegedly "concealed" such activity. *See supra* 13-15; AC ¶¶ 225–82; *In re Sanofi Sec. Litig.*, 155 F. Supp. 3d 386, 400 (S.D.N.Y. 2016) (no scienter where plaintiffs did "not plausibly allege with the requisite particularity that [defendant] paid kickbacks to third parties . . ."); *In re Axis Cap. Holdings, Ltd. Sec. Litig.*, 456 F. Supp. 2d 576, 585 (S.D.N.Y. 2006*)* (failure to plead predicate anticompetitive scheme meant that "the securities law claims premised on the nondisclosure of the alleged scheme [was] fatally flawed"). Beyond that, Plaintiffs have not pled the requisite strong inference of scienter as to any Individual Defendant or Biogen for several reasons.

First, Plaintiffs' confidential witness allegations are insufficient. The Biogen witnesses are all non-leadership former employees, and there are no allegations that any of them reported to or even *interacted* with, any Individual Defendant during the alleged class period. *See* AC ¶¶ 48, 56, 67, 87, 145–47, 162. Thus, these witnesses cannot plausibly speak to any Individual Defendant's state of mind, much less attest that any Individual Defendant admitted to any unlawful activity or to making false statements or that any Individual Defendant received from the witnesses facts contradicting their public statements. *See In re Biogen Inc. Sec. Litig.*, 193 F. Supp. 3d 5, 46 (D. Mass. 2016) (no scienter where no CW "ever spoke with one of the defendants"); *In re iRobot*

Corp. Sec. Litig., 527 F. Supp. 3d 124, 142 (D. Mass. 2021) (no scienter where CW had "no reporting line alleged to any individual related to this suit"). Nor do Plaintiffs cite any internal memo, email, or other evidence suggesting as much. *See generally* AC ¶¶ 48, 56, 67, 87, 145–47, 162. Scienter requires "clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendants were aware that they were withholding vital information or at least were warned by others that this was so." *Luongo v. Desktop Metal, Inc.*, 2023 WL 6142715, at *13 (D. Mass. Sept. 20, 2023). Plaintiffs do not come close to such a showing.[24]

Moreover, most CW allegations concerning Tecfidera describe general commercial principles or operations and are consistent with the challenged statements regarding Tecfidera's decreasing revenues. As such, these allegations do nothing to show scienter.[25] *See Auto. Indus. Pension Tr. Fund v. Textron Inc.*, 682 F.3d 34, 40 (1st Cir. 2012) (general allegations such as "the survival of the company" was "on the line" are "hardly the particularized showing required by the PSLRA"). Similarly, general allegations that "all groups at Biogen were scrambling to find ways to replace the anticipated revenue loss from Tecfidera," AC ¶ 56, or CW3's recollection of a general "instruction" from some undefined "corporate level" to "try to transfer as many patients

[24] CW4's brief tenure from "April 2018 to September 2019," AC ¶ 15, long predates the alleged class period, which begins in September 2020, *id.* ¶ 1, and they therefore "cannot have 'firsthand knowledge of the state of mind of [Biogen]'s management during [the class] period.'" *iRobot*, 527 F. Supp. 3d at 142. In any event, CW4's observations that Mr. Vounatsos said "we're going to raise prices on every drug we've been doing R&D [] on because we pay a fee to the PBMs" on certain unspecified "calls" (with no other information provided), AC ¶ 145, and views that Biogen maintained an "astronomical" price for Tecfidera so that PBMs would "receive outsized fees," *id.* ¶ 162, hardly suggests that Mr. Vounatsos thought Biogen was engaging in unlawful practices.

[25] *See* AC ¶ 48 (CW1 explaining that "the pharmaceutical industry understands that when a branded drug's patent expires and generics enter, the expected revenue will plummet within a year"); *id.* ¶ 56 (CW1 recalling that "everyone was aware there was a [patent] cliff coming"); *id.* ¶ 48 (CW2 stating that "when generics enter, there is a price drop and [product] shift . . . it's natural market dynamics"); *id.* ¶ 147 (CW5 describing the work of pricing committee).

as possible from Tecfidera to Vumerity," *id.* ¶ 67, do not suggest knowledge of illegality. *See Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 41 (1st Cir. 2017) ("usual concern by executives to improve financial results" does not support scienter).

Second, general descriptions of Biogen's contracts with PBMs, AC ¶¶ 144–46, only confirm what Biogen publicly disclosed: that PBMs "seek price discounts or rebates in connection with the placement of our products on their formularies," and that PBMs were "exerting greater pressure in pricing and usage negotiations," which "significantly increase[ed] discounts and rebates required of manufacturers." Biogen FY 2021 Form 10-K (Ex. 2), Doc. No. 49-2 at 3–4; Biogen FY 2020 Form 10-K (Ex. 1), Doc. No. 49-1 at 4–6 (same); *see also* AC ¶ 146. Such informative disclosures "undercut any inference that defendants intentionally or recklessly misled investors." *Mehta v. Ocular Therapeutix, Inc*., 955 F.3d 194, 208 (1st Cir. 2020).

Third, Plaintiffs' general assertions about Mr. Vounatsos's participation in trade groups, and "stay[ing] informed" on PBM contracts, AC ¶¶ 353–65, do not demonstrate "any firsthand knowledge" about the underlying issues, nor do they have any connection to the challenged statements. *Luongo*, 2023 WL 6142715, at *14. Indeed, that Mr. Vounatsos and Mr. McDonnell "were aware" of prior unrelated investigations and lawsuits relating to allegedly unlawful payments to *physicians*, AC ¶¶ 366–70, has no bearing on what these individuals knew or should have known about the purported illegality of Biogen's rebate payments to *PBMs*.

Finally, Plaintiffs cannot use the "core operations" doctrine to infer that, simply because of Tecfidera's importance to Biogen, the Individual Defendants "knew or were reckless in not knowing that their statements" about Tecfidera "were misleading." *See Metzler Asset Mgmt. GmbH v. Kingsley*, 305 F. Supp. 3d 181, 219 (D. Mass. 2018). Plaintiffs allege no facts regarding the percentage of Biogen's business Tecfidera represented *during the alleged class period*. *See*

AC ¶¶ 27, 56, 399–400 (data from 2016 and 2018); *In re Silverlake Grp., L.L.C. Sec. Litig.*, 2022 WL 4485815, at *9 (N.D. Cal. Sept. 27, 2022) (rejecting core operations theory absent alleged facts from "during the Class Period"). Courts are "hesitant to apply significant weight to 'core operations' allegations without other significant evidence of a defendant's intent or recklessness, or a 'plus factor.'" *Metzler*, 305 F. Supp. 3d at 219. Plaintiffs offer no such evidence. *Id*.

B. No Scienter as to Leqembi Statements

i. *Leqembi Safety Profile Statements*

Plaintiffs fail to allege that Biogen's statements concerning Eisai's assessment of the scientific data or the causes of patient deaths were anything but a scientific *opinion*. The failure to show that Defendants did not genuinely believe these statements, *see supra* 16–17, dooms Plaintiffs' claims. *See, e.g.*, *Leung*, 599 F. Supp. 3d at 63 (no scienter where statements amounted to "Plaintiff's own scientific opinion, which is insufficient to support" fraud claim).

Further, Plaintiffs' scienter allegations regarding Leqembi's safety profile fail to plead that the Individual Defendants were aware of any of the supposedly "omitted" information. The Complaint contains *no* allegations that relevant details concerning patient deaths or anecdotal opinions by certain medical professionals about the cause of those deaths were ever conveyed to the Individual Defendants. Tellingly, the most specific allegation is by a single confidential witness (CW7) who reports that they gave an autopsy report for Patient 3 to the "relevant parties at Biogen and Eisai." AC ¶ 197. Plaintiffs do not identify these parties or explain why they are "relevant," nor do they detail in any respect what information (if any) the "relevant parties" gave to the Individual Defendants. Similarly, Plaintiffs' allegations that CW6 relayed anecdotal information to individuals at Eisai do not show scienter as to the Individual Defendants *at Biogen*. *See, e.g.*,

AC ¶¶ 194–95.[26] Absent "clear allegations of admissions, internal records or witnessed discussions" that support an inference of knowledge *as to the Individual Defendants,* such allegations do nothing to support a showing of scienter. *Luongo*, 2023 WL 6142715, at *13; *Tharp v. Acacia Commc'ns, Inc.*, 321 F. Supp. 3d 206, 227, 229 (D. Mass. 2018).

In addition, Plaintiffs' allegations that Biogen was "on notice" of details concerning three unnamed patients' deaths because Eisai "admitted" in a January 6, 2023[27] press release that it "reviews all medical information associated with any fatal adverse events" are insufficient to show scienter. AC ¶¶ 371–72. Besides reiterating FDA reporting requirements, nothing in this press release provides even basic facts about the decedents, let alone details suggesting that Leqembi caused their deaths. *Id*. ¶¶ 371–74; Jan. 7, 2023 Eisai Press Release (Ex. 11), Doc. No. 49-11 at 1–2. This is insufficient to impute knowledge to anyone at Biogen, much less the Individual Defendants. *See In re Psychemedics Corp. Sec. Litig.*, 2017 WL 5159212, at *5 (D. Mass. Nov. 7, 2017) (imputation of scienter from one company to another "where the companies are separate entities" is impermissible).

Finally, Plaintiffs allege that the same press release provided a hyperlink to a December 23, 2022 press release regarding reports of a patient death, and put Biogen on "constructive notice" that "members of the scientific community" had concluded that "at least three patient deaths" were associated with Leqembi. AC ¶¶ 373–74; *see* Jan. 7, 2023 Eisai Press Release (Ex. 11), Doc. No. 49-11 at 2. In the December press release, however, Eisai expressly disagreed with those scientists,

[26] General assertions that Biogen and Eisai engaged in routine commercial interactions do not show that any Individual Defendant *at Biogen* was informed of specific information about patient deaths or any anecdotal opinions about those deaths that may have been reported to individuals at Eisai. *See* AC ¶¶ 375–80, 381–83 (describing communications between Biogen and Eisai about the commercial launch of Leqembi); *see also Tharp*, 321 F. Supp. 3d at 229.

[27] Plaintiffs refer to this press release as dated January 6, 2023, AC ¶ 371, but Eisai dates it January 7, 2023. *See* Jan. 7, 2023 Eisai Press Release (Ex. 11), Doc. No. 49-11 at 1.

stating that patient safety was its "top priority" and that "it would be inappropriate to provide additional information about specific patients or comment on information that was provided by other sources, especially those who may not have all the information necessary to make an accurate conclusion." Dec. 23, 2022 Eisai Press Release (Ex. 9), Doc. No. 49-9 at 1. This press release undermines scienter; it underscores that the cause of patient deaths was a subject of scientific debate and investigation by Eisai.

ii. *Leqembi Commercial Rollout Statements*

To allege scienter as to projections such as the 10,000-patient goal, Plaintiffs must plead with particularity either that Defendants knew the goal could not be achieved, or did not genuinely believe that it could be. *N.J. Carpenters' Pension & Annuity Funds v. Biogen Idec Inc.*, 537 F.3d 35, 55 (1st Cir. 2008) (no scienter where plaintiffs failed to establish "that defendants knew at the time" they made certain "projections" that they were misleading). But the CW allegations do not speak to the Individual Defendants' state of mind with any particularity or describe interactions directly with the Individual Defendants. Instead, they either state naked conclusions or merely express a CW's own perspectives or opinions. *See* AC ¶ 215 (CW8 estimating that half of the doctors with whom they spoke would not prescribe Leqembi).[28] It does not matter, for example, that CW11 thought the 10,000-patient goal was "crazy," *id.* ¶ 221—what matters is what the *Defendants* knew or believed to be true. *See Yan v. ReWalk Robotics Ltd.*, 973 F.3d 22, 41 (1st Cir. 2020); *In re Vertex Pharms. Inc. Sec. Litig.*, 357 F. Supp. 2d 343, 355 (D. Mass. 2005).

[28] *See also* AC ¶ 218 (CW9 asserting that registry reflected that patients had "been screened and identified as [] good candidate[s]," but "[t]hat doesn't mean they will take it."); *id.* ¶ 219 (CW10 alleging that Leqembi patient goal estimates did not consider information such as the number and location of MRI centers); *id.* ¶¶ 220–21 (CW11 alleging that Leqembi patient goal estimates did not consider "structural problems like the need for diagnostic clinics"). Personal observations by the CWs do not bear on the Individual Defendants' state of mind because the Complaint does not allege that these observations were ever shared with the Individual Defendants.

To the contrary, the more compelling inference is that Eisai and Biogen were "progressing, if fitfully at times" toward the goal and were not fraudulently reporting the rollout status. *See e.g.*, *In re Genzyme Corp.*, 2012 WL 1076124, at *11 (D. Mass. Mar. 30, 2012) (no scienter for statements about progress toward goal of FDA approval); *Bratusov v. Comscore, Inc.*, 2020 WL 3447989, at *14 (S.D.N.Y. June 24, 2020) (no scienter where CWs alleged "difficult[ies]" in achieving goal, but not that "Defendants intentionally or recklessly misled investors" regarding efforts to achieve goal). Similarly, CW8's statement about what he or she heard about progress being made toward the goal is irrelevant—CW8 worked for Eisai and does not connect their allegations at all to anyone at Biogen, much less any Individual Defendant. AC ¶ 215–16.

Finally, Mr. Viehbacher's purported statements that the rollout of Leqembi involved "an awful lot of work" related to healthcare infrastructure, may encounter "infusion capacity restrictions," and "doesn't happen overnight" only underscore that the stated goal was aspirational, and that Biogen never guaranteed success. *Id.* ¶ 214.

C. Stock Sales Allegations Do Not Support a Strong Inference of Scienter

Plaintiffs' allegations about defendants' stock sales fail to support scienter. AC ¶¶ 392–97. As an initial matter, Plaintiffs do not allege that Mr. Viehbacher sold shares during the alleged class period, which alone "undercuts an inference of scienter." *Quinones v. Frequency Therapeutics, Inc.*, 665 F. Supp. 3d 156, 175 (D. Mass. 2023); *see Loc. No. 8 IBEW Ret. Plan & Tr. v. Vertex Pharms., Inc.*, 838 F.3d 76, 84, 86 (1st Cir. 2016).

As to each of Mr. Vounatsos, Mr. McDonnell, and Dr. Singhal, Plaintiffs must allege that trading was "unusual" and "well beyond" normal patterns. *In re Focus Enhancements, Inc. Sec. Litig.*, 309 F. Supp. 2d 134, 162 (D. Mass. 2001); *see also In re Ariad Pharms., Inc.*, 98 F. Supp. 3d 147, 166 (D. Mass. 2015), *rev'd on other grounds*, *Ariad*, 842 F.3d 744 (1st Cir. 2016). The "mere fact that insider stock sales occurred," which is all Plaintiffs allege here, "does not suffice

to establish scienter." *Focus Enhancements*, 309 F. Supp. 2d at 162 (citation omitted).

Plaintiffs do not allege sufficient facts to defeat the inference from Mr. Vounatsos' and Mr. McDonnell's Form 4s that they only made automatic sales to satisfy tax obligations from vesting stock, which undermines any inference of scienter.[29] *Simon v. Abiomed, Inc.*, 37 F. Supp. 3d 499, 511, 524 (D. Mass. 2014) (deeming defendants' tax sales unsuspicious); *In re Radian Sec. Litig.*, 612 F. Supp. 2d 594, 611 (E.D. Pa. 2009). Pursuant to Biogen's Equity Plan, and consistent with IRS regulations requiring employers to withhold federal and other taxes from employee compensation, stock vesting triggers an automatic sale of shares to cover tax withholding obligations. *See* Biogen Equity Plan (Ex. 5), Doc. No. 49-5 at § 7 (describing automatic, statutory tax withholding).[30] Likewise, Plaintiffs fail to defeat the inference from SEC filings that Dr. Singhal's sales were either automatic sales to satisfy tax obligations from vesting stock *or* non-discretionary sales made pursuant to a 10b5-1 plan.[31] *Tetraphase*, 2017 WL 1946305, at *7.[32]

Further undermining any inference of scienter, Mr. Vounatsos, Mr. McDonnell, and Dr. Singhal did not sell any shares at or around the time Biogen prices peaked. *See* Biogen Historical Stock Prices (Ex. 23), Doc. No. 49-23.[33] Rather, the highest sale price obtained by any of them

---

[29] *See, e.g.*, Vounatsos Form 4s (Ex. 24), Doc. No. 49-24 at 1–9; McDonnell Form 4s (Ex. 26), Doc. No. 49-26 at 1–7. The Court can properly take judicial notice of these SEC filings. *See, e.g.*, *Crowell v. Ionics, Inc.*, 343 F. Supp. 2d 1, 15 n.7 (D. Mass. 2004).

30 The Court can properly take judicial notice of this document, which was filed with the SEC. *See, e.g.*, *Ezra Charitable Tr. v. Tyco Int'l, Ltd.*, 466 F.3d 1, 10 n.7 (1st Cir. 2006).

[31] *See, e.g.*, Singhal Form 4s (Ex. 25), Doc. No. 49-25 at 1–4, 7–14.

[32] Plaintiffs also fail to allege trading behavior for Dr. Singhal from outside the alleged class period, and thus cannot demonstrate whether any sales during this period were unusual. *See* AC ¶¶ 396–97; *Lenartz v. Am. Superconductor Corp.*, 879 F. Supp. 2d. 167, 186 (D. Mass. 2012) (Plaintiff's "burden of showing that insider sales were in fact unusual or suspicious . . . requires the plaintiff to provide information on the defendant's trading both before and after the class period[.]"). The Complaint does not allege that Dr. Singhal set up the 10b5-1 plan close in time to any alleged misstatement. *See* AC ¶¶ 396–97.

[33] The Court may take judicial notice of historical prices. *See, e.g.*, *Archdiocese of Milwaukee Supporting Fund v. Invs. Fin. Servs. Corp.*, 2007 WL 9797807, at *1 (D. Mass. July 31, 2007).

during the alleged class period for the cited sales was $286.30 per share, more than 30% below the high of $414.71 during the same period. *See* AC ¶¶ 393, 395–96; Biogen Historical Stock Prices (Ex. 23), Doc. No 49-23. *See Greebel v. FTP Software, Inc.*, 194 F.3d 185, 206 (1st Cir. 1999) (no suspicious timing when no named defendants "sold at the high points of the stock price"); *In re Ariad Pharms.*, 842 F.3d at 754 (similar).

Finally, to support scienter, Plaintiffs must "connect exact disclosures with specific conduct or inside knowledge" to the sales by each defendant. *In re Ariad Pharms.*, 98 F. Supp. 3d at 166; *Carney v. Cambridge Tech. Partners, Inc.*, 135 F. Supp. 2d 235, 256 (D. Mass. 2001). They fail to do so here. Other than a single non-discretionary trade under a 10b5-1 plan, none of the cited sales occurred near in time to any corrective disclosure or challenged statement.[34] *See Quinones*, 665 F. Supp. 3d at 176 (sales weeks after statements not suspicious); *In re Wayfair, Inc. Sec. Litig.*, 471 F. Supp. 3d 332, 347 (D. Mass. 2020). For example, Plaintiffs allege that Mr. Vounatsos made false or misleading statements at various times throughout 2020 and 2021, but his sales in those years occurred only in the month of February in connection with annual vesting and none occurred close in time to key corrective disclosure dates.[35] This trading pattern is inconsistent with any inference that Mr. Vounatsos sold to take advantage of any supposed inflationary effect of his statements. Plaintiffs similarly allege Mr. McDonnell made most of his supposed false or misleading statements in late 2020 through 2021, but do not allege Mr. McDonnell made any trades during those years. AC ¶¶ 250, 254, 258, 262, 266, 270, 395.

---

[34] Dr. Singhal sold a small number (568) of shares two days after one of her challenged statements in a non-discretionary sale pursuant to her 10b5-1 plan. *See* Singhal Form 4s (Ex. 25), Doc. No. 49-25 at 5. Her other sales were not proximate to any challenged statements. *See, e.g.*, Singhal Form 4s (Ex. 25), Doc. No. 49-25 at 1–4, 6–14. The Complaint does not allege when Dr. Singhal set up her plan. *See supra* n.32.

[35] *See* AC ¶¶ 225–26, 230, 232, 234–35, 237, 239, 241–42, 244 (alleging misstatements on September 14, 2020, October 22, 2020, February 3, 2021, April 22, 2021, July 22, 2021, September 19, 2021, and October 20, 2021); *id*. ¶¶ 393–94 (stock sales).

D. General Corporate Incentives Do Not Support a Strong Inference of Scienter

Plaintiffs also allege that, because of their compensation incentives, Messrs. Vounatsos, Viehbacher, and McDonnell (but not Dr. Singhal) "stood to gain enormously from hiding anticompetitive practices and difficulties launching Leqembi." *Id.* ¶¶ 384, 391. But executives are often compensated for company success; the fact that "compensation depended on the company's earnings . . . alone is not and cannot be enough to establish scienter." *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002).[36] Plaintiffs do not "couple the[ir] allegations . . . with 'some additional misconduct' that gives rise to an inference of scienter." *In re: Atl. Power Corp. Sec. Litig.*, 98 F. Supp. 3d 119, 133 (D. Mass. 2015) (Talwani, J.) (citations omitted).[37]

III. Plaintiffs' Section 20(a) Claims Fail

Because Plaintiffs fail to plead a Section 10(b) violation, their claim pursuant to Section 20(a) of the Exchange Act also fails as a matter of law. *See Metzler Asset Mgmt. GmbH v. Kingsley*, 928 F.3d 151, 158 n.3 (1st Cir. 2019).

CONCLUSION

For the foregoing reasons, the Complaint should be dismissed with prejudice.

---

[36] Plaintiffs vaguely invoke "respondeat superior and agency principles" but do not identify anyone other than the Individual Defendants responsible for making or overseeing the statements. AC ¶ 404. As such, these principles get them nowhere. *See, e.g.*, *Biogen Idec Inc.*, 537 F.3d at 56.

[37] Even taken collectively, Plaintiffs' allegations do not support a "cogent" inference of fraudulent intent "at least as compelling" as the non-fraudulent inferences. *Quinones v. Frequency Therapeutics, Inc.*, 106 F.4th 177, 184–85 (1st Cir. 2024). Further, because the Complaint also fails to allege the scienter of the Individual Defendants, or to identify anyone else whose scienter could be imputed to Biogen, the claims against Biogen fail as well. *Isham v. Perini Corp.*, 665 F. Supp. 2d 28, 36 (D. Mass. 2009).

Dated: February 18, 2025

Respectfully submitted,

/s/ Michael G. Bongiorno
Michael G. Bongiorno (BBO # 558748)
Timothy J. Perla (BBO # 660447)
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
Telephone: 617-526-6000
E-mail: michael.bongiorno@wilmerhale.com
E-mail: timothy.perla@wilmerhale.com

Jessica Lewis (BBO # 685549)
Wilmer Cutler Pickering Hale and Dorr LLP
2600 El Camino Real
Suite 400
Palo Alto, CA 94306
Telephone: 650-858-6000
E-mail: jessica.lewis@wilmerhale.com

Counsel for Defendants

Appendix: Challenged Statements in the First Amended Class Action Complaint (ECF No. 43)

Gray et al. v. Biogen Inc. et al. (No. 1:24-cv-12691-IT)

Compl. ¶	Source	Date	Challenged Statement
225	Morgan Stanley Global Healthcare Conference	9/14/2020	"So it depends. The erosion profile will depend on the number of generics and the aggressivity, but **we compete.** ***We have opportunities and tactics to do things the right way—the Biogen way—to compete.***"
226	Morgan Stanley Global Healthcare Conference	9/14/2020	"This is a recurrent question, and we've been always worried. ***As long as we can innovate, we continue to do well.*** And, for MS, it's a heterogeneous disease, and one product cannot be substituted by the other except the generic vis-a-via the originator potentially, but we don't see a class effect or a large impact across all the DMTs [disease modifying therapies] because, certainly, there is a generic or, certainly, there is something else. ***So this—there is no reason to believe that this will change the day after tomorrow.***"
228	Q3 2020 Press Release	10/22/2020	"Biogen is providing an update to its full year 2020 financial guidance, which was last updated in July 2020 and assumed no generic entry for TECFIDERA. ***During the third quarter of 2020, the Company began to experience the impact of multiple TECFIDERA generic entrants in the U.S.***, and this financial guidance assumes significant erosion of TECFIDERA in the fourth quarter of 2020, the pace of which is difficult to predict."
230	Q3 2020 Earnings Call	10/22/2020	"You need, obviously, to understand that ***we still have a $6 plus billion business with MS in a highly competitive environment*** where we need to absolutely resource in order to defend our leadership position. ***Vumerity*** is immaterial for now, but is signing—***is demonstrating some good signs*** and we'll come back to it. So we need to stay on and continue to resource the launch of Vumerity."

Compl. ¶	Source	Date	Challenged Statement
232	Q4 2020 Earnings Call	2/3/2021	"Now let me review our progress against our strategic priorities. First, full year MS revenues, including Ocrevus royalties, were $8.7 billion, a decrease of 6% versus the prior year. Excluding Tecfidera in the U.S., our global MS revenue remained relatively stable for both Q4 and the full year versus 2019. Despite the challenges of launching a new product during COVID-19, we were pleased to see strong improvement in trends for Vumerity, which has become the #2 MS product and the #1 oral in terms of new prescriptions in the U.S. We believe ***these results demonstrate our ability to maintain leadership and execute well despite increased competition, the erosion of Tecfidera revenue in the U.S., and COVID-19.***"
234	Q1 2021 Press Release	4/22/2021	"***Our first quarter 2021 results were consistent with our expectations across MS***, SMA, and biosimilars ***despite increased competition***."
235	Q1 2021 Earnings Call	4/22/2021	"Turning to our progress towards our strategic priorities. First, Q1 overall MS revenue, including Ocrevus royalties, was $1.7 billion. Putting aside the entry of Tecfidera in the U.S., our broader MS business continued to demonstrate resilience and progress. Excluding Tecfidera in the U.S., the number of patients on our MS products worldwide increased approximately 5% versus the prior year. . . . We were very pleased to see strong revenue growth for Vumerity, which is now the #1 oral MS product in terms of new prescription in the U.S. We believe ***this performance is a testament to a strong product profile and our team's ability to execute well, validating our plan announced mid last year to accelerate the launch of Vumerity.***"
237	Q2 2021 Earnings Call	7/22/2021	"Q2 overall MS revenue, including Ocrevus royalties, was $1.8 billion. Putting aside the entry of Tecfidera generics in the U.S., our broader MS business continued to demonstrate resilience, with a 5% increase in patients worldwide. This performance underscore our ability to execute well. We were very pleased to see continued revenue growth for Vumerity, which remains the #1 oral MS product in terms of new prescriptions in the U.S. We believe ***this performance is a testament to Vumerity's strong product profile***."

Compl. ¶	Source	Date	Challenged Statement
238	Q2 2021 Earnings Call	7/22/2021	"As Michel noted, we were very pleased with our second quarter results, as we continued to execute well. ***We continue to face competition from Tecfidera generics in the U.S.***, which impacted our year-over-year financial performance."
239	Q2 2021 Earnings Call	7/22/2021	"And, as Biogen, ***we welcome new players***. And ***some of them being competition*** and some being partners. That's good for the clinician. That's good for the patient, by definition."
241	Morgan Stanley Global Healthcare Conference	9/19/2021	"***As a company, we always welcome competition, the way we did for MS*** or SMA."
242	Morgan Stanley Global Healthcare Conference	9/19/2021	"And while we are delighted to see also a delayed uptake of Vumerity—talking about delayed uptake—***this is another case which shows, basically, the ability for the company to implement operationally and implement well.***"
244	Q3 2021 Earnings Call	10/20/2021	"***Biogen has continued to execute well and demonstrate resilience across MS***, SMA, and biosimilars, ***despite competition***."
247	2020 Form 10-K 2021 Form 10-K 2022 Form 10-K		"Product revenue reserves, which are classified as a reduction in product revenues, are generally characterized in the following categories: discounts, contractual adjustments and returns. …. Contractual adjustments primarily relate to Medicaid and managed care rebates, pharmacy rebates, co-payment (copay) assistance, Veterans Administration (VA) and Public Health Service (PHS) discounts, specialty pharmacy program fees and other governmental rebates or applicable allowances. . . . . Managed care rebates represent

Compl. ¶	Source	Date	Challenged Statement
			our estimated obligations to third parties, primarily pharmacy benefit managers. Rebate accruals are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in accrued expenses and other current liabilities. ***These rebates result from performance-based goals, formulary position and price increase limit allowances (price protection).*** The calculation of the accrual for these rebates is based on an estimate of the coverage patterns and the resulting applicable contractual rebate rate(s) to be earned over a contractual period."
250	Q3 2020 Earnings Call	10/21/2020	"Biogen had another solid quarter despite the recent entrance of generic Tecfidera and the continued impacts of COVID-19, as we continue to execute well. . . . Total revenue for Q3 was $3.4 billion, a decline of 6% versus the prior year. ***This decline was mostly driven by Tecfidera generic entry*** and is inclusive of a 1% unfavorable currency impact. Total MS revenue, including Ocrevus royalties, was $2.3 billion, a decrease of 4% versus the prior year. ***MS revenue during the third quarter began to experience the impact of the entrance of multiple generics of Tecfidera in the U.S.*** while Q3 Tecfidera revenue outside the U.S. was $283 million, representing an increase of 1% versus the prior year with continued patient growth."
251	Q3 2020 Form 10-Q	10/21/2020	"Our products continue to face increasing competition in many markets from generic versions, prodrugs and biosimilars of existing products as well as products approved under abbreviated regulatory pathways. Such products are likely to be sold at substantially lower prices than branded products. Accordingly, the introduction of such products as well as other lower-priced competing products may significantly reduce both the price that we are able to charge for our products and the volume of products we sell, which will negatively impact our revenues. In addition, when a generic version of one of our products is commercialized, it may, in some instances, be automatically substituted for our product and reduce our revenues in a short period of time.

Compl. ¶	Source	Date	Challenged Statement
			Multiple TECFIDERA generic entrants are now in the U.S. market, some of which have deeply discounted prices compared to TECFIDERA. ***The generic competition for TECFIDERA significantly reduced our TECFIDERA revenues during the third quarter of 2020*** and is expected to have a substantial negative impact on our TECFIDERA revenues for as long as there is generic competition."
252	Q3 2020 Form 10-Q	10/21/2020	• "Product revenues, net totaled $2,690.3 million for the third quarter of 2020, representing a $204.4 million, or 7.1%, decrease compared to $2,894.7 million in the same period in 2019. This decrease was primarily due to a $52.7 million, or 9.6%, decrease in SPINRAZA and a $175.3 million, or 8.1%, decrease in MS product revenues, partially offset by a $24.3 million, or 13.2%, increase in revenues from our biosimilar products. • ***The decrease in MS product revenues was primary due to a decrease in TECFIDERA demand and pricing as a result of multiple generic entrants entering the U.S. markets during the third quarter of 2020.*** * * * Fumarate revenues include sales from TECFIDERA and VUMERITY. . . . For the three and nine months ended September 30, 2020, compared to the same periods in 2019, ***the decreases of 18.7% and 1.9%, respectively, in U.S. Fumarate revenues were primarily due to a decrease in TECFIDERA demand and pricing as a result of multiple TECFIDERA generic entrants entering the U.S. market during the third quarter of 2020.*** Decreases were also due to unfavorable pricing, driven by discounts and allowances."
254	Q4 2020 Earnings Call	2/3/2021	"Biogen had another solid quarter despite the challenges from COVID-19 and Tecfidera U.S. generics, as we continue to execute well and maintain global leadership across our core businesses. . . . Total revenue for the fourth quarter of $2.9 billion declined 22% versus the prior year in both actual and constant currency. Total

Compl. ¶	Source	Date	Challenged Statement
			revenue for the full year of $13.4 billion declined 6% versus the prior year at both actual and constant currency. ***This decline was mostly driven by Tecfidera generic entry in the U.S.*** Total MS revenue for the fourth quarter, including Ocrevus royalties of $1.8 billion, decreased 24% versus the prior year at both actual and constant currency. Total MS revenue for the full year, including OCREVUS royalties of $8.7 billion, decreased 6% versus the prior year at actual currency and 5% at constant currency. ***This decline was also driven by the entrance of multiple generics of Tecfidera in the U.S.****"*
255	2020 Form 10-K	2/3/2021	"Our products continue to face increasing competition in many markets from new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways. Such products are likely to be sold at substantially lower prices than branded products. Accordingly, the introduction of such products, as well as other lower-priced competing products, may significantly reduce both the price that we are able to charge for our products and the volume of products we sell, which will negatively impact our revenues. In addition, in some markets, when a generic or biosimilar version of one of our products is commercialized, it may be automatically substituted for our product and significantly reduce our revenues in a short period of time. Multiple TECFIDERA generic entrants are now in the U.S. market and have deeply discounted prices compared to TECFIDERA. ***The generic competition for TECFIDERA significantly reduced our TECFIDERA revenues during the year ended December 31, 2020,*** and is expected to have a substantial negative impact on our TECFIDERA revenues for as long as there is generic competition."
256	2020 Form 10-K	2/3/2021	• "Product revenues, net totaled $10,692.2 million for 2020, representing a decrease of 6.0% as compared to $11,379.8 million in 2019. This decrease was primarily due to a $697.2 million, or 8.2%, decrease in MS product revenues and a $44.9 million, or 2.1%, decrease in revenues from SPINRAZA, partially offset by a $57.5 million, or 7.8%, increase in revenues

Compl. ¶	Source	Date	Challenged Statement
			from our biosimilar business. Product revenues, net, compared to the same period in 2019, further reflects the unfavorable impact of foreign currency exchange of $111.6 million. • ***The decrease in MS product revenues was primary due to a decrease in TECFIDERA demand and price as a result of multiple TECFIDERA generic entrants entering the U.S. market during the year ended December 31, 2020.*** * * * Fumarate revenues include sales from TECFIDERA and VUMERITY. . . . . For 2020 compared to 2019, ***the 17.2% decrease in U.S. Fumarate revenues was primarily due to a decrease in TECFIDERA demand and price as a result of multiple TECFIDERA generic entrants entering the U.S. market during the year ended December 31, 2020. This decrease was partially offset by an increase of approximately $60.0 million in VUMERITY sales***, which became commercially available in the U.S. in November 2019."
258	Q1 2021 Earnings Call	4/22/2021	"Biogen had another solid quarter despite the challenges from Tecfidera U.S. generics and COVID-19, as we continue to execute well across our core businesses. . . . Total revenue for the first quarter of $2.7 billion declined 24% versus the prior year at actual currency and 25% at constant currency. ***This decline was mostly driven by the continued impact of Tecfidera generics in the United States.*** Total MS revenue for the first quarter, including Ocrevus royalties of $1.7 billion, decreased 26% versus the prior year at both actual and at constant currency. ***This decline was also driven by the continued impact of Tecfidera generics in the U.S.***"
259	Q1 2021 Form 10-Q	4/22/2021	"Our products continue to face increasing competition in many markets from new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways. Such products are likely to

Compl. ¶	Source	Date	Challenged Statement
			be sold at substantially lower prices than branded products. Accordingly, the introduction of such products as well as other lower-priced competing products may significantly reduce both the price that we are able to charge for our products and the volume of products we sell, which will negatively impact our revenue. In addition, in some markets, when a generic or biosimilar version of one of our products is commercialized, it may be automatically substituted for our product and significantly reduce our revenue in a short period of time. Multiple TECFIDERA generic entrants are now in the U.S. market and have deeply discounted prices compared to TECFIDERA. ***The generic competition for TECFIDERA has significantly reduced our TECFIDERA revenue*** and is expected to have a substantial negative impact on our TECFIDERA revenue for as long as there is generic competition."
260	Q1 2021 Form 10-Q	4/22/2021	• "Product revenue, net totaled $2,211.7 million for the first quarter of 2021, representing a $692.9 million, or 23.9%, decrease compared to $2,904.6 million in the same period in 2020. This decrease was primarily due to a $634.2 million, or 30.0%, decrease in MS product revenue and a $44.5 million, or 7.9%, decrease in SPINRAZA product revenue. • ***The decrease in MS product revenue was primarily due to a decrease in U.S. TECFIDERA demand as well as higher discounts and allowances as a result of multiple TECFIDERA generic entrants in the U.S. market.*** *** * *** Fumarate revenues include sales from TECFIDERA and VUMERITY. . . . . For the three months ended March 31, 2021, compared to the same period in 2020, ***the decrease of 69.6% in U.S. Fumarate revenue was primarily due to a decrease in TECFIDERA demand as well as higher discounts and allowances as a result of multiple TECFIDERA generic entrants in the U.S. market.*** Additionally, revenue in

Compl. ¶	Source	Date	Challenged Statement
			the first quarter of 2020 reflected higher volume associated with additional shipping days. ***The decrease was partially offset by an increase in VUMERITY sales volume.***"
262	Q2 2021 Earnings Call	7/22/2021	"Total revenue for the second quarter of $2.8 billion declined 25% versus the prior year at actual currency and 26% at constant currency. ***This decline reflects the impact of Tecfidera generics***, in addition to approximately $330 million in revenue that was recorded in Q2 2020 related to the onetime license of certain manufacturing-related intellectual property."
263	Q2 2021 Form 10-Q	7/22/2021	"Our products continue to face increasing competition in many markets from new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways. Such products are likely to be sold at substantially lower prices than branded products. Accordingly, the introduction of such products as well as other lower-priced competing products may significantly reduce both the price that we are able to charge for our products and the volume of products we sell, which will negatively impact our revenue. In addition, in some markets, when a generic or biosimilar version of one of our products is commercialized, it may be automatically substituted for our product and significantly reduce our revenue in a short period of time. Multiple TECFIDERA generic entrants are now in the U.S. market and have deeply discounted prices compared to TECFIDERA. ***The generic competition for [T]ECFIDERA has significantly reduced our TECFIDERA revenue*** and is expected to have a substantial negative impact on our TECFIDERA revenue for as long as there is generic competition."
264	Q2 2021 Form 10-Q	7/22/2021	• "Product revenue, net totaled $2,236.0 million for the second quarter of 2021, representing a $559.7 million, or 20.0%, decrease compared to $2,795.7 million in the same period in 2020. This decrease was primarily due to a

Compl. ¶	Source	Date	Challenged Statement
			$597.5 million, or 28.1%, decrease in MS product revenue, partially offset by a $5.1 million, or 1.0%, increase in SPINRAZA product revenue. • ***The decrease in MS product revenue was primarily due to a decrease in U.S. TECFIDERA demand as well as higher discounts and allowances as a result of multiple TECFIDERA generic entrants in the U.S. market.*** *** * *** Fumarate revenues include sales from TECFIDERA and VUMERITY. . . . . For the three and six months ended June 30, 2021, compared to the same periods in 2020, ***the decreases of 70.8% and 70.3%, respectively, in U.S. Fumarate revenue were primarily due to a decrease in TECFIDERA demand as well as higher discounts and allowances as a result of multiple TECFIDERA generic entrants in the U.S. market. The decrease was partially offset by an increase in VUMERITY sales volume.***"
266	Q3 2021 Earnings Call	10/20/2021	"Total revenue for the third quarter of $2.8 billion declined 18% versus the prior year at both actual and constant currency and ***reflects the impact of Tecfidera generics.****"*
267	Q3 2021 Form 10-Q	10/20/2021	"Our products continue to face increasing competition in many markets from new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways. Such products are likely to be sold at substantially lower prices than branded products. Accordingly, the introduction of such products as well as other lower-priced competing products may significantly reduce both the price that we are able to charge for our products and the volume of products we sell, which will negatively impact our revenue. In addition, in some markets, when a generic or biosimilar version of one of our products is commercialized, it may be automatically substituted for our product and significantly reduce our revenue in a short period of time.

Compl. ¶	Source	Date	Challenged Statement
			Multiple TECFIDERA generic entrants are now in the U.S. market and have deeply discounted prices compared to TECFIDERA. ***The generic competition for TECFIDERA has significantly reduced our TECFIDERA revenue*** and is expected to have a substantial negative impact on our TECFIDERA revenue for as long as there is generic competition."
268	Q3 2021 Form 10-Q	10/20/2021	• "Product revenue, net totaled $2,205.7 million for the third quarter of 2021, representing a $484.6 million, or 18.0%, decrease compared to $2,690.3 million in the same period in 2020. This decrease was primarily due to a $428.9 million, or 21.6%, decrease in MS product revenue as well as a $50.3 million, or 10.2%, decrease in SPINRAZA product revenue. • ***The decrease in MS product revenue was primarily due to a decrease in U.S. TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market.*** *** * *** Fumarate revenues include sales from TECFIDERA and VUMERITY. . . . . For the three and nine months ended September 30, 2021, compared to the same periods in 2020, ***the decreases of 56% and 66%, respectively, in U.S. Fumarate revenue were primarily due to a decrease in TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market. The decrease was partially offset by an increase in VUMERITY sales volume****."*
270	Q4 2021 Earnings Call	2/3/2022	"Total revenue for the fourth quarter of $2.7 billion declined 4% versus the prior year at both actual and constant currency. Total revenue for the full year of $11 billion declined 18% versus the prior year at actual currency and 19% at constant currency. ***This decline was mostly driven by Tecfidera generic entry in the United States.***"

Compl. ¶	Source	Date	Challenged Statement
271	2021 Form 10-K	2/3/2022	"We also face increased competitive pressures from the introduction of generic versions, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways. Such products are likely to be sold at substantially lower prices than branded products, which may significantly reduce both the price that we are able to charge for our products and the volume of products we sell. In addition, in some markets, when a generic or biosimilar version of one of our products is commercialized, it may be automatically substituted for our product and significantly reduce our revenue in a short period of time. . . . Multiple TECFIDERA generic entrants are now in the U.S. market and have deeply discounted prices compared to TECFIDERA. ***The generic competition for TECFIDERA has significantly reduced our TECFIDERA revenue*** and is expected to continue to have a substantial and increasing negative impact on our U.S. TECFIDERA revenue in the future."
272	2021 Form 10-K	2/3/2022	• "Product revenue, net totaled $8,846.9 million for 2021, representing a $1,845.3 million, or 17.3%, decrease compared to $10,692.2 million in 2020. This decrease was primarily due to a $1,735.4 million, or 22.2%, decrease in MS product revenue and a $147.0 million, or 7.2%, decrease in SPINRAZA product revenue, partially offset by a $35.3 million, or 4.4%, increase in revenue from our biosimilar business. • ***The decrease in MS product revenue was primarily due to a decrease in U.S. TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market.*** *** * ***

Compl. ¶	Source	Date	Challenged Statement
			Fumarate revenue includes sales from TECFIDERA and VUMERITY. . . . . For 2021 compared to 2020, ***the 60.3% decrease in U.S. Fumarate revenue was primarily due to a decrease in TECFIDERA demand as a result of multiple TECFIDERA generic entrants entering the U.S. market. The decrease was partially offset by an increase in VUMERITY sales volumes in the U.S.***"
274	Q1 2022 Form 10-Q	5/3/2022	• "Product revenue, net totaled $2,066.3 million for the first quarter of 2022, representing a $145.4 million, or 6.6%, decrease compared to $2,211.7 million in the same period in 2021. This decrease was primarily due to an $88.8 million, or 6.0%, decrease in MS product revenue and a $48.0 million, or 9.2%, decrease in SPINRAZA product revenue. • The decrease in MS product revenue was primarily due to a decrease in rest of world Interferon demand due to increasing competition from our other MS products as well as other treatments for MS, including biosimilars. ***The decrease was also due to a decrease in U.S. TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market.*** *** * *** Fumarate revenue includes sales from TECFIDERA and VUMERITY. . . . . For the three months ended March 31, 2022, compared to the same period in 2021, the 2.7% increase in U.S. Fumarate revenue was primarily due to a favorable adjustment of prior year estimates on Medicaid-related sales of VUMERITY. ***The increase was also*** due to an increase in VUMERITY sales volumes in the U.S., ***partially offset by a decrease in TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market.***"
276	Q2 2022 Form 10-Q	7/20/2022	• "Product revenue, net totaled $2,054.9 million for the second quarter of 2022, representing a $181.1 million, or 8.1%, decrease compared to $2,236.0 million in the same period in 2021. This decrease was primarily due to a $102.6

Compl. ¶	Source	Date	Challenged Statement
			million, or 6.7%, decrease in MS product revenue and a $68.6 million, or 13.7%, decrease in SPINRAZA product revenue. • ***The decrease in MS product revenue was primarily due to a decrease in U.S. TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market*** and a decrease in Interferon demand due to competition. * * * Fumarate revenue includes sales from TECFIDERA and VUMERITY. . . . . For the three and six months ended June 30, 2022, compared to the same periods in 2021, ***the decreases of 6.9% and 2.4%, respectively, in U.S. Fumarate revenue were primarily due to decreases in TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market, partially offset by favorable pricing for TECFIDERA driven by discounts and allowances and increases in VUMERITY sales volumes.***"
278	Q3 2022 Form 10-Q	10/25/2022	• "Product revenue, net totaled $1,962.1 million for the third quarter of 2022, representing a $243.6 million, or 11.0%, decrease compared to $2,205.7 million in the same period in 2021. This decrease was primarily due to a $215.7 million, or 13.9%, decrease in MS product revenue and a $13.0 million, or 2.9%, decrease in SPINRAZA product revenue. • ***The decrease in MS product revenue was primarily due to a decrease in U.S. TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market*** and a decrease in Interferon demand due to competition. * * * Fumarate revenue includes sales from TECFIDERA and VUMERITY. . . . . For the three and nine months ended September 30, 2022, compared to the same periods in

Compl. ¶	Source	Date	Challenged Statement
			2021, ***the decreases of 26.5% and 11.4%, respectively, in U.S. Fumarate revenue were primarily due to decreases in TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market, partially offset by increases in VUMERITY sales volumes.***"
280	2022 Form 10-K	2/15/2023	"Our products and revenue streams continue to face increasing competition in many markets from the introduction of generic versions, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways. Such products are likely to be sold at substantially lower prices than branded products. Accordingly, the introduction of such products as well as other lower-priced competing products may significantly reduce both the price that we are able to charge for our products and the volume of products we sell, which will negatively impact our revenue. In addition, in some markets, when a generic or biosimilar version of one of our products is commercialized, it may be automatically substituted for our product and significantly reduce our revenue in a short period of time. . . . Multiple TECFIDERA generic entrants are now in North America, Brazil and certain E.U. countries and have deeply discounted prices compared to TECFIDERA. ***The generic competition for TECFIDERA has significantly reduced our TECFIDERA revenue*** and we expect that TECFIDERA revenue will continue to decline in the future."
281	2022 Form 10-K	2/15/2023	• "Product revenue, net totaled $7,987.8 million for 2022, representing an $859.1 million, or 9.7%, decrease compared to $8,846.9 million in 2021. This decrease was primarily due to a $666.5 million, or 10.9%, decrease in MS product revenue, a $111.6 million, or 5.9%, decrease in SPINRAZA product revenue and an $80.0 million, or 9.6%, decrease in revenue from our biosimilar business.

Compl. ¶	Source	Date	Challenged Statement
			• ***The decrease in MS product revenue of $666.5 million, or 10.9%, from $6,096.7 million in 2021 to $5,430.2 million in 2022, was primarily due to a decrease in TECFIDERA demand as a result of multiple TECFIDERA generic entrants in North America***, Brazil and certain E.U. countries, and a decrease in Interferon demand due to competition as patients transition to higher efficacy and oral MS therapies. * * * Fumarate revenue includes sales from TECFIDERA and VUMERITY. . . . . For 2022 compared to 2021, ***the 13.8% decrease in U.S. Fumarate revenue was primarily due to a decrease in TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market, partially offset by net price increases in TECFIDERA driven by lower pharmacy rebates, managed care rebates and co-pay assistance as well as an increase in VUMERITY sales volumes.***"
283	Biogen and Eisai Press Release: *"Eisai Presents Full Results of Lecanemab Phase 3 Confirmatory Clarity AD Study."*	11/29/2022	"Overall, lecanemab's ARIA incidence profile was within expectations based on the Phase 2 trial results. ARIA-E events were largely mild-to-moderate radiographically (91% of those who had ARIA-E), asymptomatic (78% of those who had ARIA-E), occurred within the first 3 months of treatment (71% of those who had ARIA-E) and resolved within 4 months of detection (81% of those who had ARIA-E). Among the 2.8% of lecanemab-treated subjects with symptomatic ARIA-E, the most commonly reported symptoms were headache, visual disturbance, and confusion. The incidence of symptomatic ARIA-H was 0.7% in the lecanemab group and 0.2% in the placebo group. No imbalance was observed in isolated ARIA-H (i.e., ARIA-H in participants who did not also experience ARIA-E) between lecanemab (8.9%) and placebo (7.8%). ARIA-E and ARIA-H were less common in ApoE4 non-carriers versus carriers, with higher frequency in ApoE4 homozygous carriers vs ApoE4 heterozygous carriers. ***In the core study and subsequent open-label extension study, rates of deaths with concurrent cerebral macrohemorrhage were 0.1%*** in both the placebo group (1/897) ***and the lecanemab group (2/1608*)**. The two cases on

Compl. ¶	Source	Date	Challenged Statement
			lecanemab occurred in the open-label extension study. ***Both cases had significant comorbidities and risk factors including anticoagulation contributing to macrohemorrhage or death. Therefore, it is Eisai's assessment that the deaths cannot be attributed to lecanemab.***"
285	Biogen and Eisai Press Release: *"FDA Approves LEQEMBI™ (lecanemab-irmb) Under the Accelerated Approval Pathway for the Treatment of Alzheimer's Disease."*	1/6/2023	"Incidence of ARIA • In Study 1 (Study 201), symptomatic ARIA occurred in 3% (5/161) of LEQEMBI-treated patients. Clinical symptoms associated with ARIA resolved in 80% of patients during the period of observation. • Including asymptomatic cases, ARIA was observed in LEQEMBI: 12% (20/161); placebo: 5% (13/245). ARIA-E was observed in LEQEMBI: 10% (16/161); placebo: 1% (2/245). ARIA-H was observed in LEQEMBI: 6% (10/161); placebo: 5% (12/245). There was no increase in isolated ARIA-H for LEQEMBI compared to placebo. • Intracerebral hemorrhage >1 cm in diameter was reported after one treatment in LEQEMBI: 1 patient; placebo: zero patients. ***Events of intracerebral hemorrhage, including fatal events, in patients taking LEQEMBI have also been reported in other studies.*** Apolipoprotein E ε4 (ApoE ε4) Carrier Status and Risk of ARIA • In Study 1, 6% (10/161) of patients in the LEQEMBI group were ApoE ε4 homozygotes, 24% (39/161) were heterozygotes, and 70% (112/161) were noncarriers. The incidence of ARIA was higher in ApoE ε4 homozygotes than in heterozygotes and noncarriers among patients treated with LEQEMBI. Of the 5 LEQEMBI-treated patients who had symptomatic ARIA, 4 were ApoE ε4 homozygotes, 2 of whom

Compl. ¶	Source	Date	Challenged Statement
			experienced severe symptoms. ***An increased incidence of symptomatic and overall ARIA in ApoE ε4 homozygotes compared to heterozygotes and noncarriers in LEQEMBI-treated patients has been reported in other studies.***"
288	Biogen Press Release: *"A statement from Biogen on LEQEMBI Pricing."*	1/6/2023	"**Important Considerations in the Study of Alzheimer's Disease** Part of Eisai's commitment to patient safety is studying the frequency, pattern, causes and risk factors of diseases and health-related events in different populations. According to the World Health Organization (WHO), dementia is the seventh leading cause of death among all diseases and the Centers for Disease Control and Prevention (CDC) reports that AD is the leading cause of dementia and the fifth leading cause of death for those 65 years and older. According to the Alzheimer's Association, the average survival after diagnosis is typically three to eleven years (median survival time: eight years). ***The patients who participate in trials for AD treatments have a relatively high rate of mortality due to the physical effects resulting from the natural progression of AD and the variety of medical conditions that develop as people continue to age.*** For example, comprehensive reviews of the scientific literature have found that patients with AD have a significantly higher incidence of hemorrhagic strokes (strokes associated with bleeding in the brain). ***When evaluating suspected serious adverse reactions, including death, of any clinical trial participants or patients prescribed medications outside clinical trials, one must consider factors like age, clinical history, concomitant medications, temporal correlation, biologic plausibility, and effects of dechallenge/rechallenge of the suspected drug.*** . . . . ARIA-H can occur spontaneously in patients with AD. ARIA-H associated with monoclonal antibodies directed against aggregated forms of beta amyloid generally occurs in association with an occurrence of ARIA-E. ARIA-H of any cause and ARIA-E can occur together. ARIA is usually asymptomatic, although serious and

Compl. ¶	Source	Date	Challenged Statement
			life-threatening events, including seizure and status epilepticus, rarely can occur. When present, reported symptoms associated with ARIA may include headache, confusion, visual changes, dizziness, nausea and gait difficulty, and focal neurologic deficits may also occur. These symptoms usually resolve over time. Intracerebral hemorrhage greater than 1 cm in diameter has been reported. ***Events of intracerebral hemorrhage, including fatal events, in patients taking LEQEMBI have also been reported.***"
290	Biogen and Eisai Press Release: *"Eisai Presented New Analyses of ARIA and QOL on Lecanemba in Clarity AD at the AD/PD™ 2023 Annual Meeting."*	3/30/2023	"In the Clarity AD study, ARIA rates were higher for patients receiving lecanemab compared to those on placebo. The objective of this analysis was to evaluate antiplatelet and anticoagulant medication use in participants who experienced either ARIA-E (edema) or ARIA-H (combined cerebral microhemorrhages, superficial siderosis, and intracerebral hemorrhages >1 cm in diameter). The risks of ARIA appear slightly higher in the placebo group with antiplatelet or with anticoagulants relative to placebo subjects not on anticoagulants (no antiplatelet or anticoagulation: 8.9%, antiplatelet: 9.7%, anticoagulation (anticoagulation alone or with antiplatelet): 10.8%). ***ARIA rates may be slightly lower in those on lecanemab treated with antiplatelet or with anticoagulation, relative to lecanemab treated subjects not with antiplatelet or with anticoagulation (no antiplatelet or anticoagulation: 21.8%, antiplatelet: 17.9%, anticoagulation: 13.3%).*** The incidence of ARIA-E was 13.1% in the lecanemab group and 1.5% in the placebo group when no antiplatelet or anticoagulant medication was used, 10.4% in the lecanemab group and 0.84% in the placebo group when antiplatelet medication was used, and 4.8% in the lecanemab group and 2.7% in the placebo group when anticoagulant medication was used. . . .

Compl. ¶	Source	Date	Challenged Statement
			In Clarity AD, ARIA did not occur more frequently in lecanemab-treated participants on antiplatelet or anticoagulant drugs compared to lecanemab-treated participants that were not on either."
292	Q1 2023 Earnings Call	4/25/2023	"I will now share highlights of additional analyses Eisai recently presented or published, consistent with both companies' commitment to transparency. . . . In addition, was also presented [sic] an updated analysis of ARIA from the CLARITY AD study to evaluate ARIA incidents in LEQEMBI-treated participants on antiplatelet or anticoagulant drugs as compared to LEQEMBI-treated participants that were not on either. ***The results*** were encouraging and ***showed that ARIA incidents were similar in the 2 groups.***"
293	Q1 2023 Earnings Call	4/25/2023	"I'll move to the next aspect. I think that you asked was about the ApoE4 homozygotes. So, Eisai presented some of these data at ADPD and also made comments on this topic. And ***they believe that really the data set was rather small. The number of ApoE4 homozygotes was quite small. They don't believe that the overall conclusions are different in terms of CLARITY AD and confidence in the data.***"
295	Q2 2023 Earnings Call	7/25/2023	"And then, of course, safety will be a big issue. When the most neurologists, if they've seen ARIA before, it's been pretty rare. I mean we do know that ARIA can occur even in the placebo group, but it's not something that'll have seen very often. And, so, this is going to be a different thing for them first to think about monitoring for safety with the MRIs. But it's one thing to be at a conference and look at safety from a data point of view. It's another thing I think to actually be looking at MRIs and seeing ARIA. ***And I think the safety benefit of lecanemab will be quite important to physicians as we go forward.***"
296	Q2 2023 Earnings Call	7/25/2023	So, overall, I think we don't fully understand the mechanism of ARIA, but the data have been replicated for Leqembi in terms of a low incidence of ARIA, in the sense

Compl. ¶	Source	Date	Challenged Statement
			that ***when you compare it with some of the other anti-amyloid/anti-beta amyloid antibodies, it is significantly lower and replicated twice.*** ***So, for example, in the Clarity AD study, we had an ARIA-E rate of about 12.6%, but with donanemab, we see an ARIA-E rate of 24%, a very similar sort of proportions with ARIA-H. So, I think that it also depends on the population that has been recruited. And as Chris mentioned, these populations have been slightly different*** with MCI being -- and the early population because we really believe that patients need to be treated earlier. So that could be playing a role. . . . ***What I think we can say is that the observation that the incidence is significantly different. And therefore, I believe that the benefit risk is also different.*** And that, I think, is what doctors should be looking at."
298	Q2 2024 Earnings Call	8/1/2024	"Lastly, while we were disappointed to learn that lecanemab received a negative opinion from the CHMP, we believe that the clinical data supports a clear favorable benefit-risk profile with a meaningful clinical benefit to patients. Furthermore, ***thousands of patients have now been treated with lecanemab globally, providing further real-world evidence on the efficacy and manageable safety profile.*** We are continuing to work with Eisai as they plan to request a reexamination of the EU filing as we work to enable access for people suffering from Alzheimer's globally."
300	Q2 2023 Earnings Call	7/25/2023	"***I will say that the whole field organization is geared up for this.*** *This* is a much more complex field organization than what you would have with a typical launch with the care navigators, with MSLs, with field reps, with regional thought leader professionals. ***So there are going to be a lot of people actually holding hands with patients, with physician practices,*** trying to help make sure that this is as seamless as possible."

Compl. ¶	Source	Date	Challenged Statement
301	Q2 2023 Earnings Call	7/25/2023	"One of the things that we have been doing is -- is really trying to figure out where are the sites that are really ready and ***actually deploying our resources to those sites with*** -- then a secondary type of approach to sites that aren't quite ready and ***helping them***. So it all depends on really how advanced the sites are, how ready they are that it's really going to define the uptake. And that's how we have to target our resources to that and really assess the site activation, if you like. But so far, we're getting a lot of positive feedback. Physicians are getting a lot of inquiries from patients. I think they will have to figure out exactly what's the right patient for this, and that's where we have to do a lot of education. And we have these online programs and other programs to help educate physicians. There's a significant amount. . . .***But so far, everything is -- as far as we're concerned, the launch is going to plan.***"
303	21st Annual Global Healthcare Conference	9/11/2023	"There certainly seems to be demand there. I don't -- I think we're confident in the demand. I think we're confident in the fact that physicians actually want to treat these patients. The CMS has moved quickly actually. And that in some ways, it shouldn't have been but kind of caught everybody off guard because ***now we can go. There's no limitation.*** *I* mean the registry seems to be pretty easy to operate. So this is now a question of filling the pipeline and pulling the patients through. And ultimately, we will see that. And ultimately, all of these physician practices will get good at this and understand this. But it is a heavy lift at the start. And I think we'll start to see that as we get through towards the end of the year. ***I think nothing that we're seeing says that the Eisai guidance can't be met, which is 10,000 patients by the end of their fiscal year, which is the end of March.***"
304	21st Annual Global	9/11/2023	"Well, ***I mean the key metric really is the site activation and the site readiness.*** And we've gone out to see 700 centers today going through the P&T committees. So

Compl. ¶	Source	Date	Challenged Statement
	Healthcare Conference		they're getting the reimbursement and weighing through all of that. ***I think the field force is just really busy on all of the logistics and getting that through.*** So I think it gets more and more. ***And that's why I think in some ways, having the target of 10,000 at the end of the first quarter is more of a relevant benchmark*** because we know it's going to be choppy up before that and there'll be some centers that are off to the races and some that will take longer and it's kind of hard to predict, to be honest, how fast it's going to go."
306	Q3 2023 Earnings Call	11/8/2023	"And in a lot of ways, we not only are pioneering science, ***we're pioneering this commercial approach.*** So of course, ***we have an aim of getting to 10,000 patients by the end of March.*** We're at 800 now. What gives us the confidence that we think we can get there? ***Well, I think we have a number of green shoots here, signs of progress. The first is, as we look at our internal metrics of intent to treat and patient demand, we are seeing all of those things progress extremely nicely.***"
308	42nd Annual Healthcare Conference	1/8/2024	"But of course, up until now, there hasn't really been any disease-modifying treatments for Alzheimer's patients. And most of them are actually being seen by primary care physicians. ***So now there's kind of a rush.*** . . . ***And so what we try to do is look upstream and see what kind of indicators we have for progress. So numbers of PET scans are going up. When we talk to people who are providing the PET scans, they're seeing lots of activity. People who are providing the blood-based biomarkers and diagnostics are seeing increased activity. We're seeing a significant increase in the numbers of new patient starts on the registry.*** And in terms of reimbursement, CMS said, okay, we're now changing and clarifying the reimbursement for PET scans, but that has to be pulled through by the

Compl. ¶	Source	Date	Challenged Statement
			dozen or so MACs that are out there. And they typically don't move that quickly, but they have moved faster than anybody has ever seen before. A lot of the IDNs were on formulary, and they have done out-of-cycle P&T committee meetings because they see it as an urgency. We certainly have patients waiting for treatment. So the real job is just establishing the care pathways, getting the policies in place and the blocking and tackling of being able to process the patients. ***So I think we're feeling pretty good. I'm looking forward to seeing how the January sales play out. A lot of positive data in December,*** but December is kind of a funny month with the holiday schedule. But I think ***we're certainly seeing an awful of tremendous progress on LEQEMBI.***"
309	42nd Annual Healthcare Conference	1/8/2024	"The next thing is a lot of physicians saying, well, okay, there's -- we can't obviously expand the number of neurologists quickly. But not everything has to be done by the neurologists. And so some of them are hiring nurse practitioners to do some of the work. ***We're not seeing any capacity constraints on PET scans, nor on MRIs, nor on infusion centers for the moment.*** So I think that will flex. So largely, it is really around the care pathways and just establishing those. ***And that increases every day, when -- the number of centers ordering from -- when we did Q3 earnings to now was up 37%, for example.*** . . . There's still -- ***we've probably got about a target of 10,000, and we're working our way through that.***"
311	Biogen Press Release: *"Biogen to Realign*	1/31/2024	"***A large portion of the resources released resulting from termination of the ADUHELM program will be redeployed in Biogen's AD franchise.***"

Compl. ¶	Source	Date	Challenged Statement
	Resources for Alzheimer's Disease Franchise"		
314	Q4 2023 Earnings Call	2/13/2024	"***Now as we look at what does drive growth, clearly, we have LEQEMBI. And I'll remind everybody that, again, we are not just pioneering in science but pioneering in commercial***."
315	Q4 2023 Earnings Call	2/13/2024	"So we've got approximately 2,000 patients on therapy at the moment. Now we don't have as companies direct access to the patient registries. You all know about the CMS registry. But there are a few other registries out there like Altinet, for example. And we have seen some analysts have been able to access that data. ***There was one analyst report of 3,300 patients on the registry, latest information that we have, and again, this is not perfect information, but we have an indication that there are about 3,800 patients as of last week on the registry.*** When you look at that, that suggests we're getting about 260, 265 patients per week in the month of January. And as far as we can tell, that's about a 56% increase over what we were seeing in December. So we are clearly seeing that there is demand for the product. We're clearly seeing that IDNs are moving to put in place the care pathways and the treatment protocols to improve access. 70 out of the top 100 IDNs have had positive P&T committee decisions. 80% of those have now actually ordered LEQEMBI. But if we talk to the people who are doing the PET scans, the MRIs, the people who sell the blood diagnostics, everybody is reporting increased activity and volume. And so -- and as you saw with Eisai's results, their belief is that for all the patients on treatment, ***they [sic] are at least three or fourfold of those who are actually in***

Compl. ¶	Source	Date	Challenged Statement
			waiting rooms. So we do believe we're making a very solid progress. And we believe that we have validated the go-to-market model."